



Comprendre le rôle de l'information et de la communication dans le passage des techniques de gestion industrielle à une culture de la qualité

Kashif Hussain

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Par

Kashif HUSSAIN

**Comprendre le rôle de l'information et de la communication
dans le passage des techniques de gestion industrielle à une
culture de la qualité :
QMI (Implémentation du Management Qualité) dans trois
entreprises multinationales**

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by

Kashif Hussain

**Understanding the role of information and
communication when moving from industrial
management techniques to a quality culture:**

**QMI (Quality Management Implementation) in three
multinational organizations**

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TOYOTA

sanofi aventis



VOLVO



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The work presented in this dissertation is entirely from the individual studies, except where otherwise stated. Where derivations are presented and the origin of the work is either wholly or in part from other sources, then full reference is given to the original author. This work has not been presented previously for any degree, nor is it at present under consideration by any other degree awarding body.

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To all those who make earth a “Quality” place to live

THE BLIND MEN AND THE ELEPHANT

By John Godfrey Saxe (1816-1887)

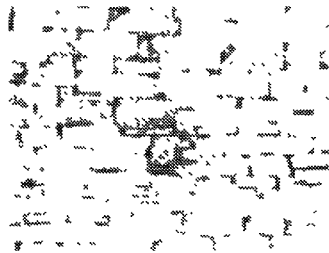
A tale "The Elephant in the Dark" in the book "Tales from Masnavi" written by Rumi has always been a source of inspiration for me since my childhood. Another version of this story was written as a poem by the name of "The Blind Men and The Elephant" by John Godfrey Saxe (1816-1887).

This story is an example of the limits of individual perception. The story indicates that reality may be viewed differently depending upon one's perspective, suggesting that what seems an absolute truth may be relative due to the deceptive nature of half-truths.

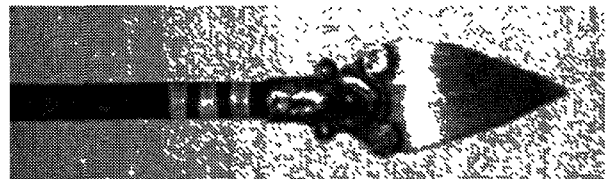
It was six of Indostan
To learning much inclined,
Who went to see the Elephant
(Though all them were blind)
That each by observation
Might satisfy his mind



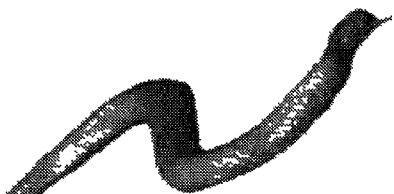
The First approached the Elephant,
And happening to fall
Against his broad and sturdy side,
At once began to bawl:
"God bless me but the Elephant
Is very like a wall."



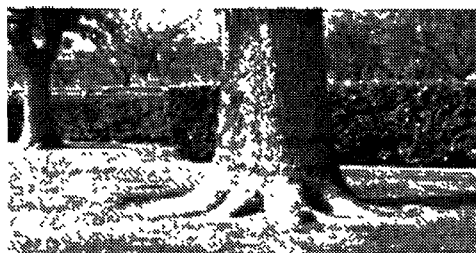
The Second, feeling of the tusk,
Cried, "Ho! What have we here
So very round and smooth and sharp?
To me 'tis mighty clear
This Wonder of an Elephant
Is very like a spear!"

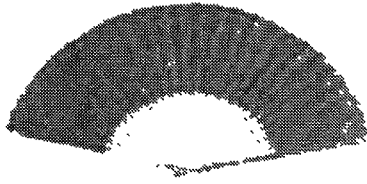


The Third approached the animal,
And happening to take
The Squirming trunk within his hands,
Thus boldly up and spake:
"I see," quoth he, "The Elephant
Is very like a snake!"



The Fourth reached out an eager hand,
And felt around the knee,
"What most this wondrous beast is like
Is mighty plain," quoth he;
"Tis clear enough the Elephant
Is very like a tree!"





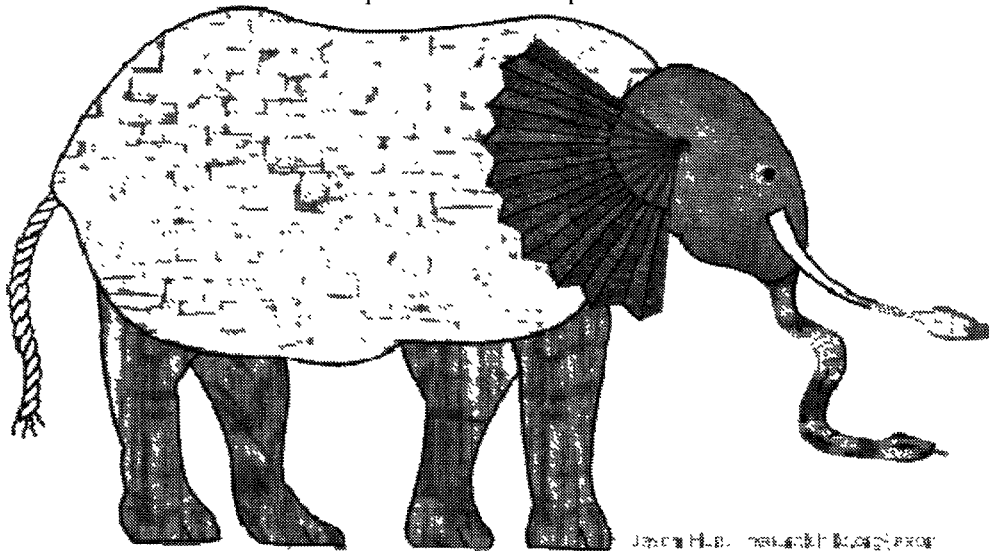
The Fifth, who chanced to touch the ear,
Said,: "E'en the blindest man
Can tell what this resembles most;
Deny the fact who can,
This marvel of an Elephant
Is very like a fan!"

The Sixth no sooner had begun
About the beast to grope,
Than, seizing on the swinging tail
That fell within his scope,
"I see," quoth he, "the Elephant
is very like a rope!"



And so these men of Indostan
Disputed loud and long,
Each of his own opinion
Exceeding stiff and strong,
Though each was partly in the right,
And all were in the Wrong!"

Moral
So oft in theologic wars,
The disputants, I ween,
Rail on in utter ignorance
Of what each other mean,
And prate about an Elephant



**FAILURE COMES IN ISOLATION - SUCCESS IS SO RARELY
ACHIEVED ALONE!**

MY THANKS TO.....

During the work on this thesis, I have benefited from a lot of dialogue with many people, who have provided inspiration and motivation. I would like to extend my heartfelt gratitude to all those who stood by me through my doctoral program. It is with a sense of achievement that I present this dissertation as part of industrial projects (2002-2007).

First and foremost, a special thanks to my principal supervisor Professor Sylvie Leleu-Merviel at University of Valenciennes, who played the key role as my supervisor throughout these industrial projects. I met Sylvie in her office shortly before I began my post graduate degree under her supervision. Her insight and creative ideas were always the inspiration for me during the research. It was as though I knew she was the right person to work with for a Ph.D. It led me to complete this dissertation work. Her brilliance and enthusiastic support not only bring out the best in her students, but also provide them with an excellent model to follow. I would like to thank for her guidance, support, encouragement, and generosity throughout all phases of this thesis and my post graduate studies. Her optimism has provided an invaluable influence on my career and outlook for the future. Despite her busy schedule, she is always available to give me advice, support and guidance during the entire period of my study.

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Academy and Society), IADIS (*International Association for the Development of Information Science*), *Handbook of Research on Informatics in Healthcare and Biomedicine*, and the *Handbook of Research on Distributed Medical Informatics and E-Health* who offered valuable suggestions, before the publications were published. I am thankful to the participants from different organizations who participated in these publications.

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In closure, I hope that all that I have learned during the past five years, as a student and as a person, would be beneficial for the indispensable development of our planet, which is struggling to be a place of quality. This will always be the main concern that will guide my work.

Lyon, February 14, 2008

Kashif Hussain

TABLE OF CONTENTS

<u>LIST OF ACRONYMS</u>	<u>16</u>
<u>SUMMARY OF THE THESIS REPORT IN FRENCH</u>	<u>19</u>
INTRODUCTION	20
PROBLEMATIQUE DE LA RECHERCHE	20
OBJECTIF DE RECHERCHE	22
LA PERTINENCE DE L'ETUDE	22
POURQUOI LA RECHERCHE INDUSTRIELLE	23
CADRE CONCEPTUEL DE L'ETUDE	23
LA COMMUNICATION AU SEIN DE L'ENTREPRISE	24
CULTURE D'ENTREPRISE	26
L'APPROCHE DU SYSTEME DE MANAGEMENT DE LA QUALITE	28
LES NORMES ISO 9000 POUR L'ENTREPRISE	30
VALIDATION DES SYSTEMES INFORMATISES	32
CAS D'ETUDES DE CETTE THESE	34
CAS D'ETUDE 1: <i>TOYOTA</i>	35
CAS D'ETUDE 2: <i>SANOFI PASTEUR</i>	35
CAS D'ETUDE 3: <i>VOLVO POWERTRAIN</i>	36
MODELISATION DE MISE EN PLACE DU SMQ	37
IDENTIFICATION DES CONSTRUCTIONS DE SQM	37
LES PHASES DE MISE EN PLACE DU MODELE DE SMQ	39
CONCLUSION	44
STRUCTURE DE THESE	45
<u>1 STUDY FRAMEWORK</u>	<u>47</u>
1.1 INTRODUCTION	48
1.2 WHY UNDERTAKE THIS RESEARCH?	49
1.3 RESEARCH ISSUE	51
1.3.1 RESEARCH OBJECTIVE	54
1.4 SCOPE AND DELIMITATION OF THE THESIS	55
1.4.1 QM ELEMENTS	55
1.4.2 QM IMPLEMENTATION	55
1.4.3 RELEVANCE OF THIS RESEARCH	56
1.5 RESEARCH STRATEGY	57
1.5.1 LITERATURE REVIEW	57
1.5.2 INFORMAL DISCUSSIONS AND OBSERVATIONS	58
1.5.3 INDUSTRIAL CASE STUDIES	59
1.6 THESIS STRUCTURE	62
<u>2 COMMUNICATION IN ORGANIZATIONS</u>	<u>64</u>
2.1 INTRODUCTION	65

2.2	COMMUNICATION IN ORGANIZATIONS	65
2.2.1	INTERNAL COMMUNICATION	68
2.2.2	EXTERNAL COMMUNICATION	71
2.3	ROLE OF COMMUNICATION IN QM	72
2.3.1	COMMUNICATION-TO-INFORM PROCESS FOR EMPLOYEE'S AWARENESS	74
2.4	ORGANIZATIONAL CULTURE	77
2.4.1	COMMUNICATION, QM AND ORGANIZATIONAL CULTURE	80
2.5	SUMMARY	81
3	<u>QM IN ORGANIZATIONS</u>	<u>82</u>
3.1	INTRODUCTION	83
3.2	QM APPROACH FOR ORGANIZATIONS	83
3.2.1	DEFINING QUALITY	84
3.2.2	DEFINING QUALITY MANAGEMENT – QM	85
3.3	LITERATURE REVIEW	88
3.3.1	TOP MANAGEMENT	88
3.3.2	PEOPLE	90
3.3.3	TRAINING AND LEARNING	90
3.3.4	PARTICIPATION AND INVOLVEMENT	93
3.3.5	CUSTOMER FOCUS	95
3.3.6	STRATEGIC QUALITY PLANNING	97
3.3.7	PROCESSES MANAGEMENT	99
3.3.8	SUMMARY OF QUALITY ELEMENTS	101
3.4	SUMMARY	103
4	<u>ISO STANDARDS FOR ORGANIZATIONS</u>	<u>104</u>
4.1	INTRODUCTION	105
4.2	ISO CERTIFICATION	105
4.2.1	ORIGINS OF ISO	106
4.2.2	WHAT ISO REQUIRES	107
4.3	LITERATURE REVIEW ON ISO STANDARDS	108
4.4	QM PRINCIPLES FOR ISO CERTIFICATION	111
4.4.1	WHAT CERTIFICATION MEANS	113
4.4.2	REASONS FOR SEEKING ISO CERTIFICATION	114
4.4.3	IMPLEMENTING AN ISO 9000 APPROACH	116
4.5	ADVANTAGES AND CRITICS OF ISO 9000	118
4.5.1	ADVANTAGES	119
4.5.2	CRITICS	121
4.6	CORE VALUES OF ISO 9000	122
4.7	SUMMARY	123
5	<u>COMPUTERIZED SYSTEM VALIDATION FOR ORGANIZATIONS</u>	<u>124</u>
5.1	INTRODUCTION	125
5.2	INTRODUCTION TO VALIDATION	125

5.3	COMPUTERIZED SYSTEM	127
5.4	VALIDATION APPROACH	129
5.5	VALIDATION APPROACH OF A COMPUTERIZED SYSTEM	131
5.6	ROLES AND RESPONSIBILITIES FOR CSV	137
5.7	CHANGE MANAGEMENT (CM)	141
5.7.1	CM FRAMEWORK	143
5.7.2	DEFINITIONS	144
5.7.3	CM PROCESS	145
5.8	DISCUSSION	146
5.9	CONCLUSION	149
5.10	SUMMARY	151
6	<u>CASE STUDY 1 – <i>TOYOTA</i> MOTOR MANUFACTURING FRANCE</u>	<u>152</u>
6.1	INTRODUCTION	153
6.2	METHODOLOGY	154
6.2.1	SAMPLING	154
6.2.2	DEMOGRAPHIC INFORMATION	154
6.2.3	CASE STUDY PROCESS	154
6.2.4	CASE STUDY DESCRIPTION	155
6.3	AN INTRODUCTION TO THE ORGANIZATION	157
6.3.1	TMMF MANUFACTURING PROCESSES	160
6.3.2	ENGINE ASSEMBLY LINE DESCRIPTION	161
6.3.3	<i>TOYOTA</i> PRODUCTION SYSTEM (TPS)	163
6.4	EVALUATION OF QMS CONSTRUCTS FOR QM IMPLEMENTATION	170
6.4.1	INTERNAL AUDITS	170
6.4.2	EVALUATION OF QUALITY ELEMENTS	179
6.4.3	TOP MANAGEMENT	179
6.4.4	STRATEGIC QUALITY PLANNING	180
6.4.5	EMPLOYEE'S TRAINING	182
6.4.6	CUSTOMER FOCUS	183
6.4.7	PROCESS MANAGEMENT	184
6.4.8	COMMUNICATION-TO-INFORM PROCESS	185
6.5	EVALUATION OF QMS IMPLEMENTATION PHASES	188
6.5.1	QUALITY INTEGRATION PHASE	188
6.5.2	QUALITY DAILY USE PHASE	190
6.5.3	QUALITY SYSTEM EVALUATION PHASE	191
6.6	IMPROVEMENT PLAN OF KEY ELEMENTS	192
6.6.1	QUALITY POLICY AWARENESS	193
6.6.2	QMS DOCUMENTATION	193
6.6.3	SPC CHARTS	196
6.6.4	IDENTIFICATION AND TRACEABILITY	199
6.6.5	CALIBRATION	199
6.6.6	TRAINING	200
6.6.7	DATABASE CREATION TO MONITOR ENGINE REPAIR ACTIVITIES	206
6.7	CONCLUSION	208
6.7.1	QMI FOR THE AUTOMOBILE INDUSTRY	209
6.7.2	IMPROVEMENT AREAS	209

7	<i>CASE STUDY 2 – SANOFI PASTEUR</i>	214
7.1	INTRODUCTION	215
7.2	METHODOLOGY	215
7.2.1	SAMPLING	216
7.2.2	CASE STUDY PROCESS	216
7.2.3	CASE STUDY DESCRIPTION	217
7.3	RELATIONSHIP WITH THE FIRST AND SECOND CASE STUDIES	219
7.4	AN INTRODUCTION TO THE ORGANIZATION	219
7.4.1	IS ORGANIZATION	221
7.4.2	ISQV (INFORMATION SOLUTIONS QUALITY AND VALIDATION)	222
7.5	IDENTIFICATION OF KEY ELEMENTS FOR IMPROVEMENTS IN <i>IS</i> QMS	224
7.6	QUALITY MANUAL FOR IS ORGANIZATION	225
7.7	COMPUTERIZED SYSTEM VALIDATION - CSV	227
7.8	FILE MANAGEMENT	228
7.8.1	ASSESSMENT OF THE FILE MANAGEMENT TOOLS	230
7.8.2	INTERVIEWS WITH IS MEMBERS	233
7.8.3	FILE MANAGEMENT TEAM PROPOSAL	234
7.8.4	FILES AND TOOLS LOCATION PROPOSAL	236
7.8.5	IMPROVEMENT PLAN FOR FILE STRUCTURE	237
7.9	<i>ISQV</i> INTRANET	240
7.9.1	INTRODUCTION	241
7.9.2	USER FRIENDLY INTRANET	241
7.9.3	INTRANET & INTERLIGO TOOL	242
7.10	EVALUATION OF QMS ELEMENTS	244
7.10.1	TOP MANAGEMENT	244
7.10.2	STRATEGIC QUALITY PLANNING	245
7.10.3	EMPLOYEE'S TRAINING	246
7.10.4	PROCESS MANAGEMENT	247
7.10.5	COMMUNICATION-TO-INFORM PROCESS	248
7.11	EVALUATION OF QMS IMPLEMENTATION PHASES	250
7.11.1	QUALITY INTEGRATION PHASE	250
7.11.2	QUALITY DAILY USE PHASE	252
7.11.3	QUALITY EVALUATION PHASE	253
7.12	CONCLUSION OF THE STUDY	254
8	<i>CASE STUDY 3 – VOLVO POWERTRAIN</i>	258
8.1	INTRODUCTION	259
8.2	METHODOLOGY	259
8.2.1	SAMPLING	259
8.2.2	CASE STUDY PROCESS	260
8.2.3	CASE STUDY DESCRIPTION	262
8.3	REASON FOR CONDUCTING THIS STUDY	263
8.4	AN INTRODUCTION TO THE ORGANIZATION	264
8.4.1	PRODUCT DEVELOPMENT LABORATORY (PDL)	265
8.4.2	PDL TEST CENTRES	266
8.5	MAINTENANCE DEPARTMENT	269

8.5.1	WHY MAINTENANCE IS REQUIRED	270
8.5.2	COMPUTERIZED MAINTENANCE MANAGEMENT SYSTEM (CMMS)	271
8.5.3	FAILURE MODES EFFECTS AND CRITICALITY ANALYSIS (FMECA)	275
8.5.4	PDL MAINTENANCE TEAMS	279
8.6	KEY PERFORMANCE INDICATORS (KPI) USED BY THE PDL DEPARTMENT	284
8.7	EVALUATION OF QUALITY ELEMENTS FOR THE QM IMPLEMENTATION	286
8.7.1	TOP MANAGEMENT	286
8.7.2	STRATEGIC QUALITY PLANNING	287
8.7.3	EMPLOYEE'S TRAINING	288
8.7.4	PROCESS MANAGEMENT	289
8.7.5	CUSTOMER FOCUS	291
8.7.6	SUPPLIER MANAGEMENT	292
8.7.7	COMMUNICATION-TO-INFORM PROCESS	292
8.8	EVALUATION OF QMS IMPLEMENTATION PHASES	295
8.8.1	QUALITY INTEGRATION PHASE	295
8.8.2	QUALITY DAILY USE PHASE	297
8.8.3	QUALITY SYSTEM EVALUATION PHASE	298
8.9	IMPROVEMENT PLAN OF KEY ELEMENTS	300
8.9.1	STEERING THE PROJECT "FMECA" TO IMPROVE EQUIPMENT RELIABILITY	302
8.9.2	TRAINING	307
8.9.3	PREVENTIVE MAINTENANCE (PM)	313
8.9.4	STANDARDIZED EQUIPMENTS	316
8.9.5	COLLABORATION WITH OTHER DEPARTMENTS	317
8.9.6	SPARE PARTS	321
8.9.7	DOCUMENTATION	324
8.9.8	CMMS	325
8.9.9	SUGGESTION SYSTEM	328
8.9.10	OTHER ACTION PLANS	330
8.10	CONCLUSION	332
9	QM IMPLEMENTATION MODELING FOR INDUSTRY	335
9.1	INTRODUCTION	336
9.2	IDENTIFICATION OF QM ELEMENTS	337
9.2.1	TOP MANAGEMENT	338
9.2.2	EMPLOYEE'S TRAINING	339
9.2.3	STRATEGIC QUALITY PLANNING	340
9.2.4	PROCESS MANAGEMENT	341
9.2.5	CUSTOMER FOCUS	342
9.2.6	COMMUNICATION-TO-INFORM PROCESS	343
9.3	MODEL FOR QM ELEMENTS	344
9.4	QM IMPLEMENTATION PHASE IN ORGANIZATIONS	346
9.4.1	WHAT IS QUALITY AWARENESS CULTURE?	347
9.4.2	WHY ORGANIZATIONS NEED QUALITY AWARENESS CULTURE?	350
9.4.3	PHASES OF QUALITY AWARENESS CULTURE	352
9.5	MODEL FORMULATION FOR QMI PHASES	361
9.6	THE ROLE OF THE QMI MODEL IN THIS STUDY	367
9.6.1	RESEARCH CONSIDERATIONS	369

9.7 CONTRIBUTION AND ASSESSMENT OF THIS STUDY	369
9.7.1 CONTRIBUTION	369
9.7.2 ASSESSMENT	370
9.7.3 LIMITATION OF THE STUDY	371
9.8 SUMMARY	372
 CONCLUSION	 374
 CONCLUSION	 375
FUTURE RESEARCH PERSPECTIVES	379
 REFERENCES	 380
 APPENDIX	 410
 APPENDIX 1: <i>TOYOTA</i> MOTOR MANUFACTURING FRANCE	 411
1.1 <i>TOYOTA</i> BUSINESS RELATIONSHIP - 2003	411
1.2 ENGINE ASSEMBLY LINE LAYOUT	412
1.3 LIST OF SPC CHARTS FOR ENGINE ASSEMBLY LINE	416
1.4 SKILL MATRIX CHART FOR EAS TEAMS	420
1.5 SOME DATABASE WINDOWS OF REPAIR ACTIVITIES	422
APPENDIX 2: <i>SANOFI PASTEUR</i>	427
2.1 PRELIMINARY DEFINITION OF TERMS USED IN PHARMACEUTICAL INDUSTRY	427
2.2 SOME EXTRACTS OF THE IS QUALITY MANUAL	431
2.3 FACTS AND FIGURES ABOUT IS FILE MANAGEMENT TOOLS	445
2.4 IS SURVEY FOR FILE MANAGEMENT	456
APPENDIX 3: <i>VOLVO</i> POWERTRAIN	468
3.1 INTRODUCTION TO <i>VOLVO</i> POWERTRAIN	468
3.2 <i>VOLVO</i> POWERTRAIN STRUCTURE	470
3.3 <i>VOLVO</i> POWERTRAIN ORGANIZATION	470
3.4 PRODUCT DEVELOPMENT (PD)	471
3.5 ENGINE TEST CENTRE PRESENTATION	472
3.6 PROCESS OF WORK ORDER OF <i>COSWIN 71</i> (IN FRENCH)	473
3.7 AN OVERVIEW OF YEARLY PM PLAN	474
3.8 AN EXAMPLE OF DASH BOARD OF PDL MAINTENANCE DEPARTMENT	475
3.9 MAINTENANCE MANAGEMENT DATA FOR THE EQUIPMENTS	476
3.10 PARETO CHART FOR OPERATIONAL MAINTENANCE FOR 2005	476
APPENDIX 4: A LIST OF THE MAJOR PARTICIPANTS IN DISCUSSION FOR QM ACTIVITIES	477
 APPENDIX 5: ASSESSMENT INSTRUMENT FOR QM ELEMENTS, QM IMPLEMENTATION AND AWARENESS CULTURE	 478
 INDEX	 487

List of acronyms

AFSSAPS: French Agency of Health Safety of Health Products

BA: Business area (terms used in *Volvo AB*)

BPF: Bonnes pratiques de fabrication

BU: Business unit (terms used in *Volvo AB*)

CFL: *Sanofi Pasteur* IS headquarter in Lyon, France

CM: Change management

CMMS: Computerized maintenance management system

CSV: Computerized system validation

DS: Design specification

EAS: Engine Assembly Line (a department in *Toyota*)

EC: European Council

EMS: Environment management system

ESFS: Special team for weekend

ETO: Engine driveline & Testing Operations (a department of PDL)

FDA: Food and Drug Administration

FMECA: Failure Mode and Effect and Cause Analysis

GL: Group leaders (terms used in *Toyota*)

GMP: Good Manufacturing Practices

GxPs: Good (Clinical, Laboratory, Manufacturing, etc

IEEE: The Institute of Electrical and Electronics Engineers

IQ: Installation qualification

IS: Information Solutions (a department in *Sanofi Aventis*)

ISO: International organization for standardization

ISQV:	Information Solutions Quality & Validation (a department of quality in Information Solutions)
IT:	Information technology
JES:	Job element sheet (terms used in <i>Toyota</i>)
JIT:	Just in time
LDG:	Laboratory Development Group (a department of PDL)
MLE:	Marcy-l'Etoile (near Lyon, France)
MTBF:	Mean time between failures
MTTR:	Mean time to repair
OQ:	Operational qualification
PDL:	Product Development Laboratory (a department in <i>Volvo AB</i>)
PM:	Preventive maintenance
POD:	Prototype order to delivery (a department of PDL)
PQ:	Performance qualification
QA:	Quality assurance
QCS:	Quality check standards (terms used in <i>Toyota</i>)
QM:	Quality management
QMI:	Quality management implementation
QMS:	Quality management system
SMQ:	Système de management de la qualité
SOP:	Standard Operating Procedures
SPC:	Statistical process control
TL:	Team leaders (terms used in <i>Toyota</i>)
TM:	Team members (terms used in <i>Toyota</i>)
TMC:	<i>Toyota</i> Motor Company
TMMF:	<i>Toyota</i> Motor Manufacturing France

TPS:	<i>Toyota</i> Production System
TQM:	Total quality management
UAT:	User acceptance testing
URS:	User requirements specification
VDR:	Val de Reuil (near Rouen, France)
VIT:	<i>Volvo</i> Information Technology (a business unit of <i>Volvo AB</i>)

Summary of the thesis report in French

Introduction

Le travail de cette thèse vise à contribuer à la recherche à la fois en communication au sein des entreprises et en management de la qualité. Cela en se fondant sur des études industrielles, notamment les projets de mise en place du système de management de la qualité (SMQ) dans l'industrie automobile et pharmaceutique. Nous réexaminons les anciennes idées, nous présentons de nouvelles voies, et nous avançons des pistes pour résoudre la problématique de la mise en place des techniques de la gestion (*management*) de la qualité au sein de l'entreprise. Ainsi, nous suggérons des modèles qui conduisent à une mise en place réussie du SMQ.

Dans le contexte actuel, les composants qualité et la communication au sein des entreprises sont des éléments clés pour faire face aux changements accélérés de l'environnement industriel. Le modèle développé vise à identifier et à analyser les principaux facteurs favorisant la mise en place du SMQ dans l'industrie automobile et pharmaceutique. Pour mieux comprendre le processus de la mise en place du SMQ dans l'industrie et pour analyser les dimensions qualité, nous avons réalisé trois études de cas (1. chaîne d'assemblage moteur, 2. département qualité et validation de système informatique, 3. département de maintenance des cellules banc d'essai) dont nous avons établi le modèle en tant que support pour améliorer les pratiques de la qualité dans l'industrie. En premier lieu, nous avons analysé l'existant de ces départements et leur relation avec d'autres départements dans le cadre du travail, puis nous avons identifié les propriétés propres aux dimensions de qualité.

Problématique de la recherche

La plupart des organisations sont impliquées dans le processus de la qualité, cependant leurs démarches peuvent être différentes. Malgré l'importance croissante donnée au management de la qualité dans l'industrie, on constate que, dans de nombreux cas, les organisations ne sont pas satisfaites des résultats obtenus [69] en comparaison des efforts déployés dans le domaine de la qualité [198].

La question qui nous a interpellé souvent au cours des années passées en industrie est : « Comment X peut être impliqué dans le processus de qualité qui conduit à l'acquisition des standards/normes de qualité Y » ? X peut être une personne, une ou plusieurs équipes, ou des services qui n'ont jamais intégré les directives de qualité proposées. Y peut être n'importe quel standard/norme de qualité comme ISO-certification, validation de systèmes informatisés, gestion de maintenance... etc. et/ou des phases des normes de qualité comme *Kaizen*, préparation d'audit, standardisation des produits, résolution des problèmes pour normaliser le processus, etc. Selon leurs expériences, plusieurs gestionnaires reconnaissent, intuitivement, qu'un certain nombre de composants de SMQ ont peu d'influence (ou de valeur) sur la réalisation des objectifs de l'organisation [198]. Les chercheurs ont démontré que l'échec de SMQ était dû aux problèmes de mise en place comme le manque d'appui et/ou engagement de la direction supérieure [69] [151], la gestion inefficace du changement relative à la situation de l'entreprise [326], l'utilisation et le déploiement insatisfaisants des outils de contrôle qualité du processus [142], les stratégies de la mise en place du SMQ, [92] et enfin un manque de communication au sein de l'entreprise [188] [198]. Il n'y a aucun consensus quant à la solution aux problèmes mentionnés ci-dessus [374]. La mise en place réussie du SMQ au sein de l'entreprise exige que tous les facteurs critiques soient adressés de la bonne façon. La problématique de recherche est focalisée sur la modélisation du SMQ (chapitre neuf) dans l'organisation, elle consiste à étudier le cadre pratique et les composantes pour mieux orienter les efforts de SMQ et le rôle de la communication au sein des entreprises.

Les premières questions peuvent être traduites ainsi « Y a-t-il un besoin de modèles nouveaux pour mettre en place un SMQ dans l'industrie, de manière à faciliter et à examiner le modèle de mise en œuvre du SMQ ? ». Le travail envisagé consiste à étudier dans quelles conditions le problème est réel, et si le développement du modèle SMQ y sera pertinent. Pour cela, j'ai d'abord étudié les approches développées par les experts du domaine et la littérature scientifique. Mon but n'était pas seulement d'acquérir des connaissances en la matière, mais de découvrir également les questions et le potentiel de recherche associés. Ainsi, à ce moment-là, j'ai développé plusieurs pistes de réflexion, questions et hypothèses au

sujet du SMQ. Dans cette optique, j'explore le thème SMQ en me focalisant sur la communication au sein des entreprises, les pratiques de qualité, les phases de mise en place du SMQ, les conditions de réussite et la diffusion de la culture qualité.

Objectif de recherche

Fondé sur la communication au sein des entreprises, les composantes de qualité et la mise en place de SMQ en milieu industriel, ce travail de recherche vise l'objectif suivant :

- Développer un modèle pour mettre en place un SMQ en milieu industriel.

Ainsi, il est possible d'identifier le champ de connaissance lié à la communication au sein des entreprises et les normes qualité dans le milieu industriel.

La pertinence de l'étude

Cette étude peut être vue comme une des premières dédiée aux composantes de la qualité, et à la communication en vue d'informer les salariés pour la mise en place du SMQ dans l'industrie en se fondant sur des études de cas, issues de l'industrie automobile et pharmaceutique, et en proposant un modèle générique pour ces cas d'études. Bien que la plupart des études en management et en SMQ traitent des principales composantes de la qualité, y compris les diverses études liées à la certification ISO, il y a peu d'études sur le thème de la mise en place (*implementation*) de SMQ, surtout en prenant en compte la prise de conscience (*awareness*) de la qualité par la communication au sein des entreprises. Cette étude permet de comprendre les pratiques en matière de SMQ et la communication pour l'instaurer dans différents environnements industriels (chaîne d'assemblage moteur, système d'information, banc d'essai). Le choix de ces trois études de cas semble approprié pour les raisons citées ci-après. D'abord, la chaîne d'assemblage moteur est considérée comme le cœur de l'industrie automobile. En outre, le système d'information sert de référence à n'importe quel système informatisé. La

validation d'un tel système, en l'associant avec le modèle qualité, est importante en vue d'introduire un facteur de conformité dans le SMQ. L'étude relative au banc d'essai est extrêmement importante pour la performance, la durabilité du moteur, et aussi pour développer le modèle.

Pourquoi la recherche industrielle

Nombreux sont les articles et les thèses qui traitent le thème de la qualité et la mise en place de SMQ en utilisant soit les enquêtes par le questionnaire, soit les entretiens avec des experts pour recueillir des informations sur des pratiques de SMQ en milieu industriel. Tous ces outils ont leurs propres avantages et limites dépendant de la nature de l'échantillon, des contraintes et des objectifs de la recherche. J'ai préféré travailler en industrie directement au lieu d'utiliser d'autres outils pour mes résultats de recherche parce que il est plus important de savoir ce qui se produit dans l'industrie et comment le message de la qualité peut être intégré, tout en restant très proche des départements engagés dans l'étude de cas (c.-à-d. chaîne d'assemblage moteur, département de qualité et validation, département de maintenance). Ce choix a été adopté après une analyse de la littérature. Cependant, chaque instrument présente plusieurs limites (la subjectivité et les pré-jugements personnels, ...) qui peuvent influencer l'analyse des résultats. Néanmoins, on ne peut pas exclure ces inconvénients des autres instruments possibles (enquêtes par questionnaire, etc.).

Cadre conceptuel de l'étude

Après avoir passé en revue la littérature existante sur le SMQ, ce projet de recherche vise à contribuer à un certain développement théorique, qui examine systématiquement les effets de la mise en place de SMQ et propose l'analyse des approches actuelles de SMQ. J'ai puisé dans une bibliographie étendue pour extraire, d'une part, les éléments utiles qui ont été développés pour construire le modèle (présenté dans le chapitre 9). D'autre part, pour intégrer les fondements théoriques, et des pratiques qualités, dans le cadre conceptuel de la recherche.

Puisque tous les éléments extraits de la bibliographie ont été soutenus par divers chercheurs, aussi vais-je les intégrer dans le modèle proposé en chapitre

neuf. En outre, cette recherche envisage de développer un modèle de mise en place d'un SMQ et de proposer des pistes de recherche. Pour les praticiens industriels, cette recherche permet d'offrir quelques nouveaux points de vue pour le processus de mise en place de SMQ. L'explication est rapportée dans l'étude des cas (présentée en chapitre six, sept et huit) et chapitre neuf (développement d'un modèle de mise en place des normes de SMQ au sein de l'entreprise).

Sur le plan du développement du travail de recherche, trois études de cas industrielles ont été réalisées où différents départements ont été impliqués de diverses manières pour mettre en place un SMQ. J'ai cherché à comprendre comment les industries ont appliqué des principes du SMQ dans leurs départements pour consigner des résultats sous la forme de modèle de mise en place du SMQ.

La Communication au sein de l'entreprise

Rôle de la communication dans le SMQ

Le rôle de la communication est souvent ignoré dans un programme SMQ malgré l'importance concrète de la communication de groupe, la résolution des problèmes en équipe, le système de suggestions. Peu de recherches sont faites en observant le rôle de communication dans le SMQ [11] [378]. Les articles de recherches théoriques et empiriques qui traitent le SMQ dans les organismes sont presque inexistantes [11] et par conséquent, très peu d'articles visant la théorie de communication dans l'organisation sont disponibles [11] [110] [111] [378]. Selon Allen et Brady, la plupart des auteurs cités dans les livres de SMQ reconnaissent facilement l'importance de la communication. Cependant, comme mentionné précédemment, très peu d'études de recherche sont disponibles jusqu'à maintenant [11].

Kim (2005) traite les distinctions entre les types de communications au sein des entreprises, par exemple les communications horizontale et verticale [192]. Selon lui, « la communication horizontale est reliée à l'interaction informelle

interpersonnelle et socio-émotionnelle avec les collègues proches et autres dans l'entreprise, et qui sont au même niveau ». Kim décrit la communication verticale en tant que « communication relative à l'emploi à travers la hiérarchie de l'organisme et peut s'étendre aux employés recevant des informations sur la stratégie de l'organisation, capables de donner une réaction ascendante et un conseil à la direction » [192] [250] [251]. Quelques chercheurs ont expliqué que la communication est une spécificité culturelle [334]. Selon Le Moëne, des entreprises sont impliquées dans l'environnement culturel tout en s'adaptant à lui selon l'internationalisation et en maintenant l'efficacité de l'entreprise [211]. Selon Cerkevic, il y a trois étapes principales dans la qualité de la communication. Lancer la démarche, la faire vivre, la rendre durable et perpétuelle [62].

La communication interne

Les communications internes dans un organisme constituent un sous domaine spécialisé des sciences de la communication qui examine de quelle manière et sous quelles conditions les salariés communiquent dans l'entreprise, ainsi que la nature des communications efficaces dans les organisations [140]. Les communications internes dans un organisme peuvent inclure toutes les actions de l'information et de la communication favorisées par la hiérarchie de gestion, du directeur de communication interne ou du département qui a la responsabilité d'implémenter la politique de communication de l'organisme. Toutes ces actions doivent faciliter l'adhésion des employés envers des valeurs d'organisation et des objectifs. La communication interne facilite le travail d'équipe et permet aux équipes de trouver la manière dont l'organisme va lancer sa stratégie [253]. L'information interne communiquée par une organisation devrait créer un repère d'identité de la part des différents employés, un sentiment d'unité dans l'organisme et un appui pour les objectifs de l'organisme considéré.

La communication externe

La communication externe inclut tous les types de communications (relations publiques, auteurs ou lobbying, etc..) qui ajoutent de la valeur à l'entreprise et reflètent une meilleure image de ses produits ou marques [253]. Les communications externes soutiennent les opérations commerciales en contribuant à l'amélioration de la connaissance de l'organisation et de ses produits, en renforçant les produits de l'entreprise, et en créant une compréhension de leurs efforts de la part des clients, des actionnaires et de la société. Les communications avec les actionnaires, le marché financier et les médias devraient également contribuer à une bonne évaluation de l'entreprise et créer des relations à long terme, aussi bien que la confiance dans les valeurs que représente l'entreprise.

Culture d'entreprise

La culture d'entreprise n'est pas homogène, uniforme, normalisée ou statique [189]. Elle évoluera avec le temps et il semble raisonnable d'affirmer que le système culturel montrera des changements continus et progressifs, interrompus occasionnellement par un changement radical plus périodique [371] [374]. La culture peut être caractérisée comme un ensemble commun de valeurs, d'idées sociales, d'attitudes, de normes ou de croyances que partagent les membres des organismes [395]. La culture forte peut être définie comme les normes et les valeurs, qui sont clairement comprises et ont une influence significative sur le comportement des employés [197]. Deux chercheurs ont observé et interrogé 5000 directeurs en Amérique du Nord pour cerner le travail essentiel de la direction. Ils sont parvenus à la conclusion que la direction est responsable du développement d'un type de culture dans l'entreprise qui contribue au bon fonctionnement de l'organisme [39].

Lien de la communication et du SMQ avec la culture d'entreprise

La communication de la direction et des autres employés dans une organisation s'est avérée être un facteur déterminant de la culture de l'organisation [256] [308]. La culture d'un organisme peut être changée et améliorée en changeant les modèles de communication. Par conséquent, il est impératif de créer et développer une culture qui encourage la communication, la formation, l'apprentissage et le partage des connaissances, ce qui permettra aux employés de voir l'ensemble plutôt que leur partie en adoptant une attitude myope [196]. La structure de l'organisation délimite les responsabilités et les voies de communication et peut faciliter la circulation et le traitement de l'information [122]. Brown et Starkey (1994) ont indiqué que la culture d'une organisation est un facteur important influant sur les attitudes, et les systèmes et processus relatifs à la gestion de l'information et de la communication [50]. Leur étude a montré que la culture configure et développe la communication, qui influence la nature de l'information (qualité et quantité) distribuée dans l'organisme.

L'étude de SMQ dans une perspective culturelle suit une compréhension de la dimension culture d'entreprise. L'accent est mis sur la compréhension du rôle de la culture de l'organisme qui joue dans l'implémentation de SMQ. Dans ce domaine de recherche, la culture de l'organisation est supposée constituer un facteur majeur empêchant ou soutenant l'implémentation réussie de SMQ. La recherche de Hildebrandt sur la culture de qualité et le SMQ a souligné l'importance de la culture d'entreprise et la découverte des hypothèses culturelles fondamentales courantes en tant que condition primaire pour l'implémentation réussie de SMQ [150]. Divers chercheurs fournissent une analyse détaillée de la culture de l'organisation dans la recherche sur le SMQ [191] [223]. La culture d'entreprise est une vraie priorité de la direction et peut limiter le changement de l'organisme [233]. Les chercheurs précisent que soit la culture forte de SMQ est toujours avantageuse pour l'organisme dans la formation de la culture stratégique, soit elle partage seulement un sous-ensemble dans l'implémentation de SMQ

[197]. La culture de l'organisme peut être affectée différemment par l'introduction d'un système de SMQ, peut être plus ou moins réceptive à SMQ, et en conséquence l'implémentation de SMQ peut avoir différents résultats dans l'organisme. Les chercheurs ont précisé quel type de culture est essentiel [84], ainsi que les effets de culture de l'organisme sur les succès et les échecs de l'implémentation de SQM [191].

L'approche du système de management de la qualité

Le terme « management de la qualité » n'a pas une unique définition convenue ni même de définition exacte ou précise, alors qu'est-ce qui le rend efficace, et comment devrait-il être mis en application ? Même les experts en matière de qualité ont semblé lutter pour définir le terme. Ceci pourrait être dû au fait que le terme « qualité » sous-tend une signification différente pour chaque personne, qui peut avoir comme conséquence différents modèles du SMQ. Cependant, ils partagent un ensemble commun de suppositions et de prescriptions qui souvent apparaissent sous forme de TQM, ISO, Kaizen, etc. et qui rentrent toutes dans l'approche du SMQ.

Définition de la qualité

Le terme « qualité » est souvent employé dans un sens vague, et aucune définition standard n'existe. Il n'y a aucun accord universel sur ce que signifie le terme « qualité » [402]. C'est une notion subjective, relative et toujours rapportée à un usage et à un client, c'est-à-dire à un besoin [158]. En général, la qualité peut être considérée comme la capacité d'un produit/service à satisfaire les besoins et les attentes définis par des clients et des parties prenantes – soit des clients internes (employés, directeurs) ou des clients externes (qui veulent en avoir pour leur argent). Dans le sens large, la qualité est une chose qui peut toujours être améliorée [166] ; elle répond à l'exactitude du besoin cerné [176] [179], à la conformité aux besoins [75], à l'opinion du client [114] et / ou à l'uniformité par rapport à une cible identifiée [87]. Sa définition normalisée donnée par l'AFNOR

est « l'aptitude d'un ensemble de caractéristiques intrinsèques à satisfaire des exigences ou des attentes formulées, habituellement implicites, ou imposées ». La qualité est une mesure de performance expérimentée par les clients. Dans toutes les définitions qui existent, il apparaît que le centre d'intérêt est le client [216] [168].

Définition du SMQ

Les chercheurs ont indiqué qu'il n'y a aucun consensus sur la définition du SMQ, puisqu'elle varie suivant l'approche adoptée pour la qualité [304]. SMQ est un concept de gestion qui concentre les efforts collectifs des directeurs et des employés pour satisfaire les attentes du client en améliorant continuellement les opérations, la gestion du processus, et les produits [33]. Les chercheurs ont suggéré dans la littérature la plus large sur la gestion de la qualité que le SMQ a une composition duelle ; un côté dur (Hard) et un côté mou (soft) [135]. Le côté dur se concentre sur des systèmes, des outils et des techniques, et sur l'établissement de standards de performance. Le côté mou concerne des attitudes et des valeurs accentuées pour mobiliser tous les employés autour du but de l'amélioration continue et à s'engager activement à travers la participation et la prise de responsabilité [385] [150] [309] [45].

Dans notre cas, le SMQ est défini comme suit : une approche de gestion pour l'amélioration continue de la performance globale en se fondant sur six concepts fondamentaux :

- La direction
- Le personnel (formation et apprentissage)
- La stratégie et la planification de la qualité
- L'orientation des clients
- La gestion des processus

- La communication pour informer

Ainsi, la qualité n'est pas un programme, mais une transformation. En tant qu'élément de cet effort, la direction doit identifier le besoin d'évaluation, de planification stratégique, et le développement d'une approche d'intégration à long terme dans l'organisation. La direction a besoin d'établir des politiques définissant les positions que l'organisation prendra à l'égard de la qualité. La direction a également besoin de cultiver une orientation du client et de fournir à tous les employés la formation, l'apprentissage en permanence et la communication pour l'informer.

Les normes ISO 9000 pour l'entreprise

Bien que l'acquisition de la certification ISO 9000 soit optionnelle, elle devient une nécessité en raison de la pression de la concurrence volontaire des marchés globaux et locaux. Selon l'approche d'ISO 9000, n'importe quel organisme peut établir un système de qualité en mettant en application l'ensemble formé de huit aspects spécifiques qui constituent la qualité. L'objectif de ces directives est de commander la variation des spécifications exigées d'un produit par le service. La description des huit directives est mentionnée ci-dessous [168] :

- Orientation vers le client : les organismes ont besoin de comprendre les besoins des clients actuels et futurs, ils doivent répondre à des exigences des clients et tâcher de surpasser les espérances des clients.
- Engagement et appui de la direction/management : les chefs doivent établir et maintenir l'environnement interne dans lequel les employés peuvent devenir entièrement impliqués pour atteindre les objectifs de l'organisation.
- Participation des personnes : les personnes à tous les niveaux sont le noyau d'un organisme et leur pleine participation est nécessaire à la stratégie de l'organisme. La formation du personnel pour comprendre les aspects opérationnels du SMQ et l'appui sont nécessaires.

- Approche processus : un résultat désiré peut être acquis plus expéditivement quand des actions, les activités et les ressources reliées sont contrôlées ensemble comme un processus qui implique de projeter et de commander, avec inspection et évaluation des performances.
- Approche systématisée de gestion : identifier, comprendre et gérer des processus corrélés comme un système contribue à l'efficacité et l'efficacité de l'organisation en ayant atteint ses objectifs.
- Amélioration continue : l'amélioration continue de l'exécution globale de l'organisme devrait être un but durable de l'organisme.
- Approche logique de la prise de décision : des décisions efficaces sont fondées sur l'analyse des données, des faits et de l'information.
- Rapports/relations mutuellement salutaires avec les fournisseurs : un organisme et ses fournisseurs sont interdépendants et un rapport mutuellement salutaire augmente la capacité de tous les deux à créer la valeur.

Pourquoi la certification ISO

La certification ISO vise à donner aux clients la confiance en leurs fournisseurs par l'assurance que les fournisseurs ont mis en place des processus de SMQ qui garantissent l'uniformité du produit ou du service. L'ISO encourage mais elle-même de toute façon ne certifie pas, assure ou ne surveille pas la qualité du produit. La certification signifie la conformité apurée à un niveau appliqué générique de la série ISO. La certification ISO, par elle-même, ne garantit pas que la qualité des produits ou les services d'un organisme soient meilleurs que ceux des autres organismes [324] [47].

Certains chercheurs suggèrent que la certification est souvent fondée sur des pressions institutionnelles [141]. D'autres proposent que les sociétés puissent adopter ISO en visant la certification comme condition de normalisation ou d'exportation [16] [359]. La Communauté Européenne a exigé des sociétés qui

vendent des « produits sensibles de sûreté » dans la Communauté Européenne de se conformer aux normes ISO 9000 (ou de soumettre régulièrement des échantillons pour examen). Par conséquent, la norme volontaire est liée à la pression de normalisation [72].

Avantages et limites d'ISO 9000

Les avantages de l'ISO 9000 incluent l'uniformité dans les procédures et la pratique par un engagement explicite à de bonnes procédures de gestion, à des améliorations continues, à une meilleure image [392] [93], à des rôles définis pour chaque membre d'équipe, à l'élimination des pratiques non pertinentes et enfin à la suppression du travail gaspillé [154]. Malgré son acceptation internationale répandue, ISO est entouré par la polémique et la critique. Une critique répandue sur l'ISO est qu'elle n'est pas reliée assez directement à la qualité du produit [336]. Par exemple, un organisme certifié peut comporter des processus et proposer des produits de moindre qualité parce que la certification n'indique pas à un organisme comment concevoir des produits plus efficaces et plus fiables. La certification n'exige pas non plus que les sociétés démontrent que leurs clients sont satisfaits. En plus, un focus sur la documentation a, en soi, conduit quelques directeurs à considérer ISO 9000 comme rien de plus qu'un processus « sauf-conduit » pour que les bureaucrates n'y trouvent rien à redire [47].

Validation des systèmes informatisés

Cette section définit la démarche et les responsabilités nécessaires à la validation des systèmes informatisés utilisés par les entreprises pharmaceutiques dans un contexte réglementé (BPx/GxP - Bonnes pratiques de fabrication, Good Manufacturing Practices, etc). La validation d'un système informatisé a pour objectifs de :

- s'assurer que le système informatisé et l'utilisation qui en est faite sont conformes aux exigences réglementaires applicables ;

- s'assurer que le système est conforme aux exigences fonctionnelles, de fiabilité, d'intégrité et de sécurité ;
- s'assurer que l'exploitation et les évolutions de ce système sont maîtrisées.

La validation des systèmes informatisés est une obligation réglementaire.

Principe de validation

Les étapes minimum de validation à respecter sont :

1. Définition des besoins : établir le document définissant les besoins et les contraintes des utilisateurs, et permettant de consulter les fournisseurs.
2. Evaluation du fournisseur : évaluer le niveau qualité du fournisseur en général (système qualité, pratiques de spécifications, de conception, de développement, de tests et de maîtrise des modifications) et la mise en œuvre de ces dispositions pour le système informatique considéré.
3. Spécification Fonctionnelle : établir la référence définissant exactement la fourniture système et logicielle en termes de fonctions à réaliser.
4. Organisation de la validation : formaliser le processus, la stratégie de validation, les responsabilités et les critères d'acceptation du système informatisé.
5. Suivi de la réalisation et des tests projets : s'assurer du bon déroulement de la réalisation et des tests projets des équipements et des logiciels composant le système informatisé.
6. Qualification d'Installation : vérifier que le système informatisé (équipements et logiciels) est installé conformément aux exigences du constructeur et de l'utilisateur, et que la documentation du fournisseur est présente.

7. Qualification Opérationnelle : vérifier que le système ou une partie du système fonctionne, dans des conditions de simulation, conformément à ses spécifications fonctionnelles préalablement établies.
8. Qualification de Performance : vérification que le système informatisé fonctionne, dans des conditions réelles d'exploitation, tel que demandé (comportement stable, documents opérationnels en place, personnel formé) et que ses résultats (données réelles) sont conformes à l'attendu. Elle permet de vérifier que le système informatisé est maîtrisé par l'organisation utilisatrice, dans son environnement réel d'utilisation.
9. Bilan de la validation : conclure et synthétiser les étapes de validation d'un système.
10. Formation : les personnes appelées à utiliser les systèmes informatisés, à les valider ou à en assurer la maintenance et l'évolution, doivent être formées préalablement conformément à la procédure d'entreprise, et ces formations documentées conformément à la procédure d'entreprise. Cette formation doit reposer sur des documents à jour par rapport au système / logiciel concerné (support formel de formation, manuel d'utilisation, instruction, ...).
11. Gestion de modifications : garantir la maîtrise des modifications effectuées et la prise en compte du processus validé de système. Ces objectifs se traduisent par la traçabilité et l'enregistrement de modifications et la mesure de l'impact sur le système.
12. Maintenance : maintenir le système de bonnes conditions opérationnelles jusqu'à la fin de vie du système.

Cas d'études de cette thèse

Des études de cas appropriées ont été menées dans l'industrie automobile et l'industrie pharmaceutique en France pour étudier et comprendre la mise en place du SMQ dans la pratique et pour observer les effets des composants qualité. A l'aide de ces études de cas, un modèle de mise en place de SMQ a été développé en

chapitre neuf afin de répondre à l'objectif de cette recherche. Au sein des trois organisations, j'ai travaillé sur plusieurs projets (les activités qualité pour la certification ISO 9001 : 2000 liée à l'assemblage moteur, à la validation de système informatisé, à la maintenance préventive et réparatrice, et à l'amélioration de processus) dans le but commun de réaliser les objectifs des organisations et d'apporter des éléments de réponse à certains objectifs de recherche.

Cas d'étude 1: Toyota

J'ai participé à une introduction à la certification ISO 9001 en assemblage moteur (EAS – Engine Assembly Shop) au sein de *Toyota* pendant l'année 2002-2003. Cette organisation a joué un rôle significatif dans ma recherche industrielle, les pratiques en SMQ utilisées chez *Toyota* ont fourni un cadre favorable pour le développement précoce de mes recherches dans le domaine de la mise en place du SMQ. *Toyota* était dans cette période la troisième entreprise mondiale de l'automobile - et numéro deux aujourd'hui -, connue pour sa production de qualité (système de production de *Toyota* - TPS utilisé dans le monde entier aujourd'hui). La décision pour acquérir la certification ISO 9001 pour *Toyota* France a été prise en 2001. La décision de l'installation d'EAS a été prise à ce moment-là, et le processus de certification n'a débuté qu'à la mi-2002. La première étude de cas réalisée est la certification d'EAS. Les détails de cette étude de cas sont présentés dans le chapitre six. Le système qualité fondé sur ISO 9001 a été considéré comme un bloc construisant le SMQ, et le TPS, qui existait déjà, a fourni l'appui nécessaire pour le SMQ. Le département EAS a été préparé pour apporter le soutien nécessaire aux employés en élaborant des plans d'action sur la façon dont la certification ISO peut être mise en place pour améliorer les activités de production, en développant les programmes de formation, et en initiant un programme étendu d'évaluation via les séries d'audits internes.

Cas d'étude 2: Sanofi Pasteur

Sanofi Pasteur, représentant l'industrie des vaccins de l'entreprise du Groupe *Sanofi Aventis*, est la plus grande entreprise au monde consacrée aux

vaccins humains. Les travaux sur la SMQ ont été faits avec le département « ISQV - Information Solutions Qualité et Validation » pour développer la méthodologie de validation du système informatisé. La direction s'intéressait à travailler sur une véritable « trousse de validation » (kit de validation) qui peut formaliser et améliorer les processus existants concernant la validation, et aussi assurer un réel soutien pour le système de validation informatisé (CSV) et la gestion du changement (CM). J'ai travaillé pendant 2005-2006 afin de fournir un appui au département ISQV en étudiant le CSV, le CM, et la gestion de la documentation pour mener à bien mon étude de cas. Ici, les pratiques de gestion de la qualité utilisées dans les pratiques pharmaceutiques fournissent un contexte pour le système d'informatisation. Je me suis engagé avec le service « ISQV » pour fournir un élément fondamental dans le SMQ pharmaceutique. Nous avons à assister les départements des IS en introduisant des plans d'action sur les moyens d'utilisation de « trousse validation / kit de validation », en assurant la gestion de la documentation pour certains outils afin d'améliorer les activités de l'entreprise en offrant des recommandations, des programmes de formation, et par le lancement de vastes ateliers sur la qualité.

Cas d'étude 3: Volvo Powertrain

Volvo AB, le deuxième plus grand fabricant de camions lourds au monde, travaille constamment pour encourager et gérer la qualité du travail dans le but d'améliorer la satisfaction du client et son efficacité interne. J'ai travaillé avec *Volvo Powertrain* pour déployer des outils qualité pour la gestion de la maintenance et avec les différents départements (développement, maintenance et opération). La direction de *Volvo* désirait une amélioration des activités liées au maintien de moyens techniques, et de gestion liée à la maintenance. La mission de déployer des outils qualité, y compris AMDEC (analyse de mode de défaillance, de leurs effets et de leur criticité) et GMAO (gestion de maintenance assistée par l'ordinateur), était d'optimiser la maintenance pour leur banc d'essai. L'analyse du AMDEC a fourni de manière claire des actions à effectuer pour faire face à des problèmes de maintenance. Nous nous sommes concentrés sur la maintenance préventive et corrective afin d'améliorer le rendement opérationnel. Plusieurs

formations ont été élaborées pour le département, et de nombreuses fiches d'instructions pour faciliter le travail, l'amélioration des systèmes, etc ..., ont été proposées, mises en œuvre, et réalisées. L'un des objectifs était de contribuer de manière différente aux activités de la gestion de la qualité telles que le suivi des indicateurs de la qualité de la maintenance.

Modélisation de mise en place du SMQ

L'implémentation réussie du SMQ dans l'industrie dépend de plusieurs facteurs. L'aboutissement de la mise en place du SMQ dépend d'une interaction complexe et multidimensionnelle entre le SMQ et les utilisateurs. Afin de comprendre les résultats des efforts de mise en place du SMQ, on doit considérer les rapports entre les dimensions de qualité et leurs interactions. Dans cette partie, nous rapportons des résultats issus de nos trois différentes études de cas, fondées sur le travail en milieu industriel et une revue de la littérature de recherche.

Identification des constructions de SQM

Après une étude détaillée de la littérature présentée en chapitres deux, trois, quatre et cinq, et trois cas d'études industrielles présentés en chapitre six, sept et huit, six composantes du SMQ ont été identifiées. Ainsi, dans cette étude, le SMQ se compose de six composantes ; ce sont les « dimensions qualité » exigées pour le SMQ. Mettre en place un SMQ est possible en déployant toutes ces composantes au travers des différentes phases.

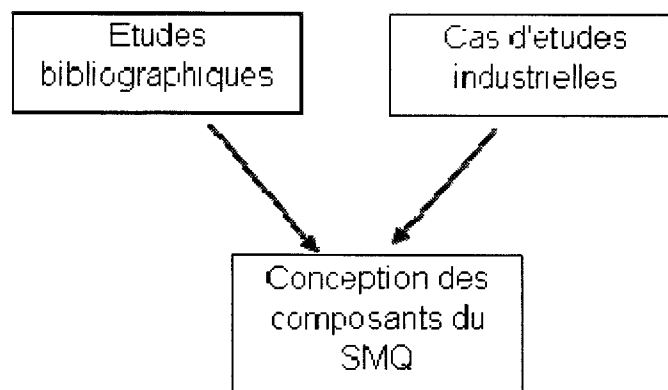


Figure-1: Processus d'identification des composants de SMQ

Ces éléments sont à nouveau répétés :

1. Leadership / engagement de la direction
2. Formation et apprentissage des employés
3. Stratégie et planification de la qualité
4. Orientation clients
5. Gestion des processus
6. Communication-pour-informer

Toutes ces composantes qualité ont besoin d'être articulées ensemble afin d'obtenir des résultats concrets. En général, la qualité a révélé des obstacles dans les projets : le manque de communication entre les départements / groupes / équipes, le manque de confiance dans le système qualité, l'impression de gaspillage de temps, une documentation trop abondante, ainsi qu'une mauvaise interprétation du vocabulaire de la qualité. Le problème principal est de développer la culture de la qualité au travers des différentes organisations : direction / employés. Je considère les composantes ci-dessus comme fondamentales pour mesurer la pertinence du SMQ. À moins que la direction soit déterminée à travailler sur toutes les composantes avec un engagement fort, n'importe quel effort pour présenter le SMQ dans l'organisme sera vain. Sans fonctionnement de toutes les composantes d'une manière interactive, on ne pourrait pas mettre en application le SMQ dans les entreprises. Le manque d'engagement de la direction semble être l'obstacle principal pour résoudre ce dilemme. Nous proposons, pour résoudre le problème de mise en place du SMQ, certains points déjà abordés dans les chapitres 2, 3, 4, 5, 6, 7, et 8 :

Moins la démarche du SMQ est accompagnée par des **composantes de qualité**, moins le problème de mise en place du SMQ est résolu.

Moins la démarche du SMQ est accompagnée par la **direction**, moins le problème de mise en place du SMQ est résolu.

Moins la démarche du SMQ est accompagnée par des **formations et participations des employés**, moins le problème de mise en place de SMQ est résolu.

Moins la démarche du SMQ est accompagnée par la **planification stratégique de qualité**, moins le problème de mise en place de SMQ est résolu.

Moins la démarche de SMQ est accompagnée par la **gestion des processus**, moins le problème de mise en place de SMQ est résolu.

Moins la démarche du SMQ est accompagnée par l'**orientation client**, moins le problème de mise en place de SMQ est résolu.

Moins la démarche du SMQ est accompagnée par la **communication-pour-informer**, moins le problème de mise en place d'un SMQ est résolu.

Les phases de mise en place du modèle de SMQ

La littérature et les cas d'étude ont traité des composants qui sont nécessaires pour le développement du SMQ. Maintenant, cette partie met en avant notre modèle de recherche. Quelques études ont identifié que le manque de mise en place des pratiques de gestion demeure la barrière principale pour améliorer les pratiques proposées. Mais, d'une manière générale, la mise en place planifiée du SMQ aide à augmenter la fluidité d'information se partageant dans l'organisme. Le modèle de mise en place du SMQ réside sous l'influence de la conscience d'une culture qualité (*quality awareness culture*).

Etre conscient d'une culture qualité?

Celle-ci signifie créer un certain état d'environnement de la connaissance dans l'organisme. L'objectif principal est de participer ensemble aux activités qualité en partageant des ressources et la connaissance. La conscience qualité est la vision partagée entre la direction et les salariés pour la mise en place du système qualité. Ceci signifie qu'il existe le besoin de fournir une compréhension juste des

aspects de base de la qualité pour toutes ces personnes. C'est une tâche qui requiert la participation de tout le monde dans le système qualité en raison de plusieurs aspects (intégration de la qualité, pratiques quotidiennes, encouragement, participation, patience, planification à long terme, etc..). En termes de gestion de la qualité, l'aspect principal est de faire participer les personnes dans le processus qualité par la formation à temps et par l'information, et de les autoriser à s'investir activement. De ce fait, trois phases sont nécessaires afin de développer une atmosphère coopérative où la conscience qualité (mise en place de SMQ) se déplace autour des personnes.

Intégration qualité?

L'intégration qualité est considérée du fait que les employés impliqués dans le processus qualité en connaissent le système, le procédé et l'environnement opérationnel. Le vocabulaire révélateur d'un langage commun et de qualité crée un cadre mutuel en vue des opérations et du but de l'organisme. Ceci augmente les bases d'interaction dans et entre tous les départements pour communiquer efficacement et répondre à l'information spécifique de la même façon [127]. Chaque fois que n'importe quelle pratique nouvelle (par exemple les normes ISO 9001) est proposée, il y a alors la nécessité de trouver un ajustement aux nouvelles règles et de rompre avec ses vieilles habitudes de fonctionnement dans l'organisme (car les anciennes habitudes caractérisent la connaissance qui a été utilisée pour faire face aux conditions antérieures). Dans divers cas, la mise en place de nouvelles pratiques semble être sensible tandis que l'assimilation exige l'équilibre uniforme entre la nouvelle pratique et les pratiques existantes. Ainsi nous considérons que **moins la phase d'intégration qualité est accompagnée pour une norme du SMQ, moins le problème de mise en place de SMQ est résolu.**

Qualité dans la vie quotidienne?

L'utilisation quotidienne de la qualité signifie que toute formalisation et approbation des procédures est applicable dans la routine quotidienne. Ainsi,

aucun besoin de se dépêcher à la dernière minute pour se préparer aux audits externes. Sans préparation antérieure, les employés peuvent faire ce qui est exigé [344]. Si les employés travaillent uniquement pour l'audit cela signifie que le système a existé, mais pas pour être employé dans la vie quotidienne. Ainsi le système mis en place avec l'intégration qualité devrait être utilisé dans des activités quotidiennes. Naveh (2005) a écrit que la pratique quotidienne est l'application régulière d'une norme de manière convenable [117] [107] - à tel point que cela devient une partie des routines quotidiennes d'un organisme [74] [263]. Ainsi nous considérons que **moins la phase d'utilisation qualité dans la vie quotidienne est accompagnée pour une norme du SMQ, moins le problème de mise en place du SMQ est résolu.**

Évaluation du système de management qualité

L'intégration qualité et l'utilisation quotidienne sont parmi les étapes critiques, pas assez cependant pour mettre en place entièrement le SMQ. L'évaluation aide à surveiller la satisfaction des ayants droit, ce qui exige l'évaluation systématique concernant la perception quant aux niveaux auxquels leurs besoins et espoirs ont été comblés [168]. L'évaluation est le seul instrument qui aide à mesurer le niveau de satisfaction des spécifications de l'organisme [177]. L'évaluation de la situation dans les procédures de gestion de la qualité d'une entreprise fournit une base importante pour la société afin d'améliorer ses procédures de gestion de qualité. Une telle information d'évaluation devrait être communiquée aux employés afin d'encourager ces derniers à réaliser de meilleurs services. Ainsi nous considérons que **moins la phase d'évaluation qualité est accompagnée pour une norme du SMQ, moins le problème de mise en place du SMQ est résolu.**

En l'appuyant sur les éléments identifiés ci-dessus, les organismes peuvent employer un modèle pour réaliser la prise de conscience qualité afin de mettre en place entièrement le modèle qualité mentionné ci-dessous :

Phase de la mise en place du SMQ (système de management qualité)

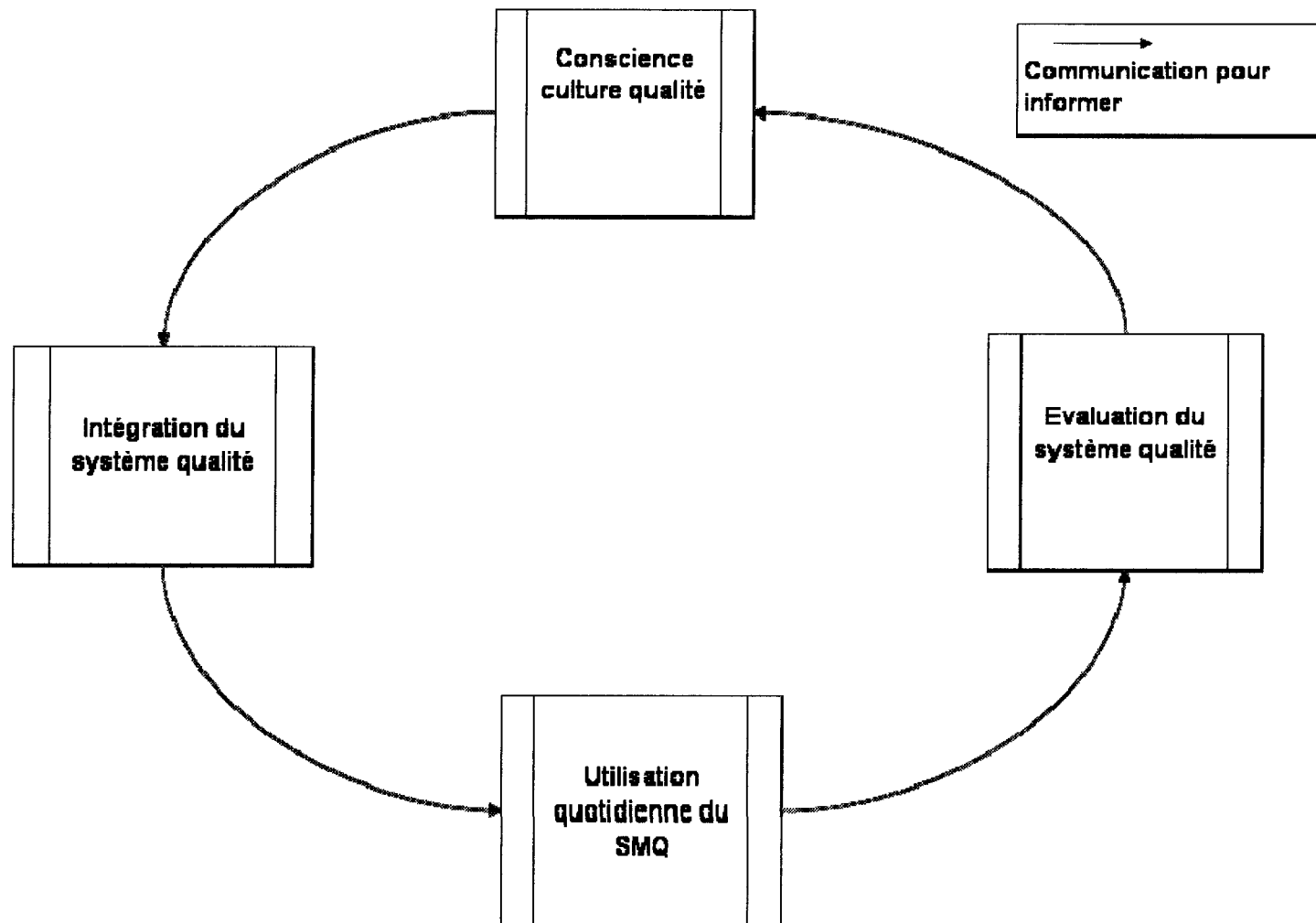


Figure-2: Étapes de décomposition en phases de la mise en place du SMQ par une conscience qualité

Phases de la mise en place du SMQ (système de management qualité)

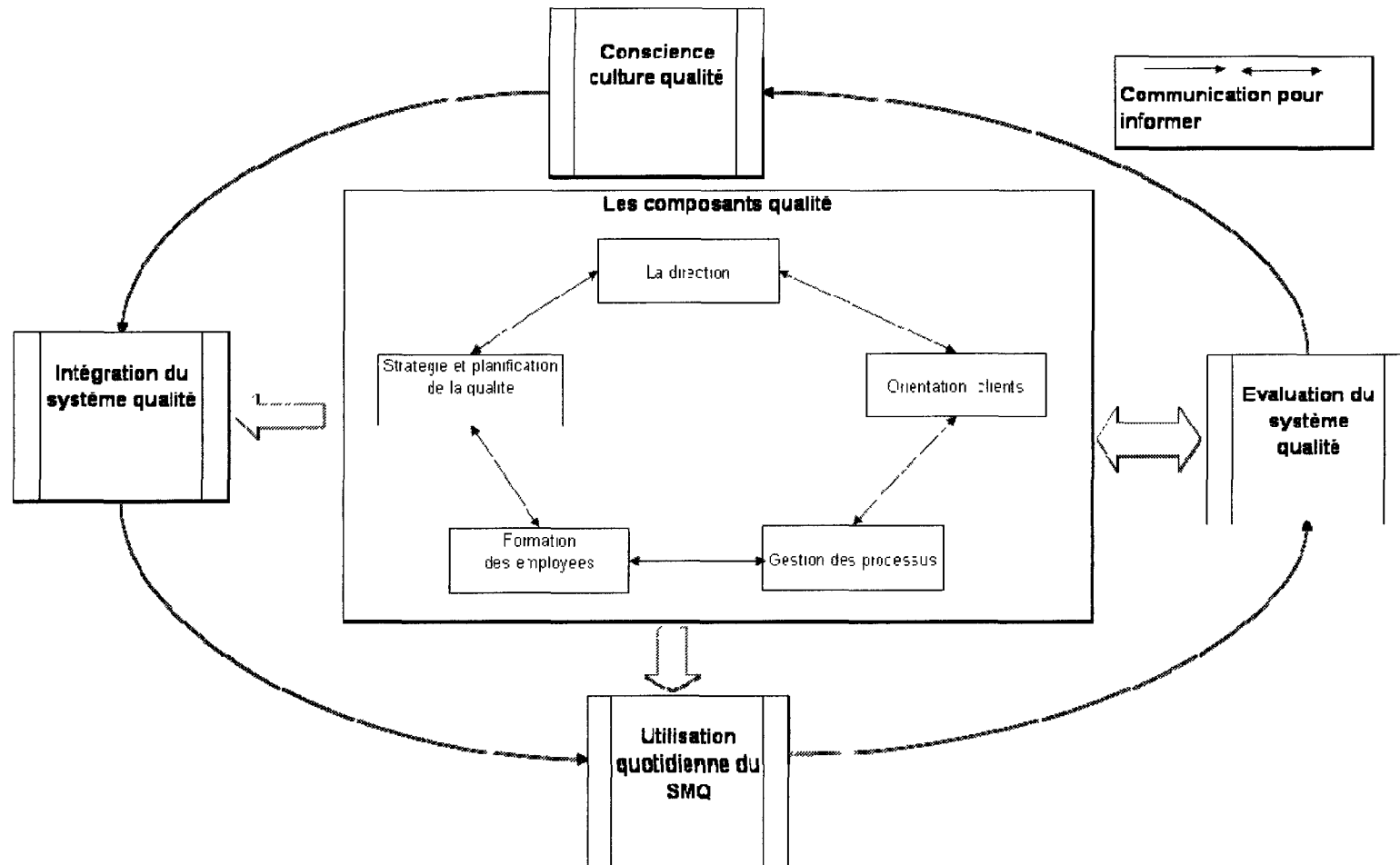


Figure-3: Composants de SMQ et modèle de mise en place de la qualité par la prise de conscience de la culture qualité

S'avèrent importants pour le modèle proposé deux points clés qui sont les suivants :

Moins la démarche de SMQ est accompagnée par des composants qualité, moins le problème de mise en place du SMQ est résolu.

Moins la démarche de SMQ est accompagnée par des phases de mise en place du SMQ, moins le problème de mise en place du SMQ est résolu.

Les cinq boîtes au centre contiennent des composants de SMQ. Sur le côté extérieur, il y a les trois boîtes représentant les phases pour la mise en place du SMQ, représenté en tant que quatrième boîte par la conscience de la culture de qualité. La mise en place du SMQ dépend de la façon dont les composants qualité sont assimilés relativement aux phases mentionnées. Nous fournissons ainsi une démarche qui structure la mise en place de l'instrument SMQ en trois étapes. L'objectif final est d'observer l'impact des phases sur la mise en place, qui dépend des composants qualité et des phases de conscience de qualité dans ce modèle.

Conclusion

Les études de cas démontrent que ce modèle de mise en place du SMQ peut être employé pour évaluer les composants qualités, les phases d'implantation ainsi que la culture qualité, afin d'observer les facteurs continus d'amélioration des organismes, ainsi que pour mesurer les améliorations au cours du temps. Finalement ce modèle sera utilisé pour identifier précisément les secteurs ayant besoin d'amélioration, et le niveau de qualité atteint par les différentes organisations en employant soigneusement les ressources disponibles. Toutes les structures fonctionnent de manières différentes selon leur secteur d'activités, leurs objectifs, l'environnement, le niveau de technologie utilisé, le personnel, etc. Ainsi aucun modèle général n'existe ni ne peut être appliqué comme règle standard pour la mise en place de SMQ. Par ailleurs, les organismes appliquent différents modèles SMQ selon leurs besoins, et des critères fondés sur l'activité industrielle. Il n'y a pas d'obligation pour l'organisation à adopter le modèle SMQ complet, mais une combinaison appropriée et le mélange avec des pratiques en matière de qualité d'organisation déjà adoptées peuvent mener à répartir judicieusement les ressources organisationnelles.

Structure de thèse

Le chapitre 1 donne une description du cadre de l'étude ainsi que l'objectif de la recherche.

Le chapitre 2 décrit la communication au sein de l'entreprise (communication interne et externe dans les organisations) - et examine son rôle dans la gestion de la qualité. Le rôle de la communication dans le SMQ est également présenté.

Le chapitre 3 décrit le concept de la gestion de la qualité fondé sur la littérature et les travaux de recherche relatifs au domaine du SMQ. Ainsi, les composants de la gestion de la qualité sont présentés.

Le chapitre 4 décrit le concept de l'ISO 9001 fondé sur l'étude d'une littérature spécialisée. L'approche ISO envers la gestion de la qualité est traitée afin d'établir la relation entre qualité et management.

Le chapitre 5 décrit le concept de validation de système informatisé fondé sur la littérature dans le domaine de l'industrie pharmaceutique. Ainsi, le concept de la gestion de la modification est défini.

Le chapitre 6, 7 et 8 présente les perspectives de cette méthodologie de recherche industrielle au sein de l'entreprise (*Toyota*, *Sanofi Pasteur* et *Volvo Powertrain*). Les stratégies adoptées dans cette recherche sont examinées en détail. Les solutions pour l'accès, l'évaluation et l'analyse du SMQ, et la manière de conduire l'étude de cas sont décrites dans ces chapitres. Les propositions d'améliorations et les limitations de la recherche sont également abordées. Ces chapitres donnent aussi un exemple d'utilisation de cette implémentation du SMQ dans la pratique.

Le chapitre 9 identifie les six concepts et trois phases de SMQ utiles pour répondre à la question de recherche. En se fondant sur l'étude de la littérature, et sur les études des cas industriels, le modèle reliant les concepts du SMQ et la communication au sein de l'entreprise pour l'implémentation du SMQ est

développé. Le chapitre présente aussi l'évaluation des instruments de mesure de l'implémentation de la gestion de la qualité.

Le chapitre 10 présente la conclusion de recherche en termes de mise en place de SMQ.

1 Study Framework

1.1 Introduction

This chapter gives a brief description of the research. Section 1.2 discusses the background for the research. Section 1.3 describes the research issues with research objectives presented in this dissertation. Section 1.4 presents the scope of the study and significance. Section 1.5 describes the research strategy adopted. Section 1.6 provides the thesis structure.

International markets, heavy competition, and supplier pressures have led to various visible drives for excellence. Business today compels to prepare oneself with cutting edge technology, skilled employees, committed management, and a viable quality management system in adopting new management philosophies. International competition requires high levels of quality from organizations [175]. Organizations, therefore, pay considerable attention to quality management (QM) philosophies, procedures, tools and techniques to compete in the intense global competition. In this thesis phrase “QM” covers all kinds of QM systems in all kinds of organizations. In this thesis phrase “short-term planning refers to six months, medium-term planning refers to two years and long term planning refers to five year planning. This was taken in accordance with the case study organizations QM approach.

Quality has been a subject of major interest for communication sciences as well as for management theorists [377]. Organizations are now embedding QM practices and communication activities into their routine business as essential to remaining competitive. Today, QM has emerged as a successful organizational approach in its rapid development over the last two decades. The QM theories became popular in the United States and Europe most likely as a result of the success of Japanese firms in a number of international markets [206]. The modern roots of QM originated around 1949 in Japan from engineering activities, mostly statistical quality control to more managerial concepts like quality circles, and Just-In-Time, encompassing broad organizational concept [191] [290]. In the early days of World War II, the US defense department used quality sampling procedures in decisions on whether to accept or reject munitions, thus causing defense suppliers to be more concerned with quality assurance [128]. The Japanese approach towards QM had a strong impact on organizations and management

practices, where it had been considered as “the second industrial revolution” [184]. Quality scholars and practitioners have developed an increasing diversity and specialization in quality vocabulary and concepts. Quality approaches have been extensively used and treated in a large body of academic and industrial work as a revolutionary approach to effective management [5].

1.2 Why undertake this research?

I was involved in QM activities before completing my graduation (four year engineering degree) studies from the *National University of Sciences and Technology* from Pakistan in 1997. In the last year of my graduation in mechanical engineering, I had an opportunity to work as a trainee engineer for six months in the cement industry where I came to know ISO 9002 certification and quality management system (QMS) in organizations. During this training period, I had various formal discussions with engineers and learnt about the complexities involved in managing and understanding QMS in an industrial organization. I was attracted by these activities and this was the beginning of my quality journey. I was told that process improvement and service conformance by reducing uncertainty in manufacturing processes was possible with QM. I participated in QM training sessions in which various benefits of QM were explained including: economical; increased productivity; a way to improve process, product and work environment; satisfy clients; etc. After completion of my graduation, I joined the same company as an Assistant Manager (Mechanical). However, in addition to mechanical maintenance, I was engaged in the development of the management of quality system with the departmental head of the packing plant department. The company sought to acquire the ISO 9002 certification. At that time, the certification was not very common in Pakistan and my company was among the first ones that were certified at that time. Initially, for a young mechanical engineer in *Askari Cement Limited*, QM was the key to provide solutions to many management problems. With the passage of time, uncountable experiences, numerous discussions, literature and reading technical literature made plain to me the various complexities involved when dealing with human nature and the interactions among teams in organization involved and the various external factors. This made it more difficult to crack the shell of QMS to implement in industry.

Three years spent in *Askari Cement Limited* did not provide all those benefits and promise the QM team was conveying during the training sessions in the company (increased productivity; a way to improve process, product and work environment; satisfy clients; etc). I continued attending numerous training sessions on quality and about management to better focus on QM. What was not very clear was how to implement the QM standards in industry? During my stay in industry, it was found that QM procedures were not implemented and even rejected. During an internal audit in *Askari Cement Limited*, when a team was asked to produce necessary QM documentation, it had all procedures. However, verification demonstrated gaps between the procedures and implementation in the department. Not a single audit was observed without these differences in written procedures and its implementation. The implementation phase is the heart of any QM. This increased my quest to find ways of QM implementation. I have to say, after ten years of my experience, the QM principles and standards are based more or less on the same grounds. There is no dramatic change in these QM standards. There was something missing in quality management and that was the implementation phase in industry.

Most organizations and their managers are aware of the need to adopt quality practices and its implementation in order to succeed in today's ever-changing context [286]. The wide acceptance and use of the QM offers additional motivation for the research. Moreover, ISO 9000:2000 QMS standard developments in the recent years play a vital role in selecting an ISO certification as a QM standard in the automobile industry. In addition, computerized system validation (CSV) is considered as the key part of QM thus remained an attractive factor in selecting the pharmaceutical industry case study. Details about CSV are presented in chapter five. The final motivational factor was the opportunity to work with giant industrial players like *Toyota Motor Manufacturing France*, *Sanofi Pasteur* and *Volvo AB* to validate the study.

In *Toyota Motor Manufacturing France*, at the assembly and quality department, I worked on analyzing the existing QMS in order to go towards the ISO 9001:2000 and 14001 certifications. At that time, I focused on quality constructs and quality culture concepts in order to understand its importance in the QMS implementation.

In *Sanofi Aventis*, in the quality and validation department of *Sanofi Pasteur*, I worked on improving the methodology for computerized system validation, necessary to ensuring that the computerized system complies with the regulatory requirements. While working with multi-site departments, I tried to focus on quality culture concepts that I considered vital to QMS implementation. I was strongly backed by my manager and directors to propose solutions.

In *Volvo AB*, in the maintenance department of engine test bench of the *Volvo Powertrain*, I worked on analyzing the existing maintenance practices in order to optimize maintenance management. The major axes of this study for QM implementation were improving maintenance strategies like inventory issue, quality tools utilization, and for Computerized maintenance management system (presented in chapter eight - section 8.5) to improve coordination among other departments concerned with maintenance.

I utilized my previous knowledge, experience and was conscious of my personal bias to critically understand QM of the above organizations and worked on applying the model that I deemed effective. I had gone through several elements of QM in order to observe and understand the implementation of QM in industry.

1.3 Research issue

Most organizations are involved in quality issues, however, their way to use this approach may differ. Despite the growing importance of QM in industry, it is interesting to find that, in many cases, organizations have been disappointed by the lack of expected and significant results [69]. QM has met with mixed reviews from organizations that have attempted to understand and to implement QM for organizational improvement [188]. QM experts were unable to provide satisfactory answers for the inconsistent success of QM implementation [198]. Top management dissatisfied with QM because organizations reported that QM failed to improve process and reduce defects, even after they were using the QM for almost two and a-half years on average [69]. The most commonly asked quality question during my several years of work in industry was “How ABC can be involved in quality matters since we are trying hard to acquire the XYZ quality

standards”. Here ABC can be “any single person, any team or a group of several teams or other departments who never care about the quality guidelines issued” and XYZ can be “any quality standard including ISO-certification, system verification and validation, etc” and or sub-phases of quality standards like kaizen, audit preparation, product standardization, problem solving to standardize the process, etc”. Experienced and influential managers intuitively acknowledge that a number of the QM practices had little or no value in attaining their organizational objectives [198]. Researchers demonstrated that QM failure was due to implementation problems like lack of top management support [69] [151], ineffective positioning of change initiatives relative to organization’s situation [326], inadequate use and deployment of quality tools of process control [142] strategies to implement QM [92] and a lack of communication throughout the organization [188]. There is no consensus, concerning the solution of all the above mentioned problems [374]. Successful implementation of QM requires that all critical factors be addressed in an adequate way. Among these factors are training in support of the transition to QM, performance evaluation process and content aligned with the nature of a QM organization, etc [188]. Some studies identified that failure to implement management practices related to quality remained the barrier to seek the benefits of the QM practices [194] [267]. Very few articles are available that focus on communication aspects in implementing QM in organizations [11]. Despite the number of publications and research about QM, little industrial work has been conducted in establishing the relationship between communication aspects and implementation of any QM standards (ISO, etc.). What is notable, however, is that the role of communication in QM has received little attention, although use of group communication is fundamental QM practice [374]. Communication-based concepts are rarely raised in the discussion of QM in industry [11] [374].

One of the reasons is that organizations do not think ahead about how they are going to manage awareness (presented in chapter nine) and timely learning and training [75][76] (presented in chapters three, four, and five) for all their employees involved in QM activities. Awareness is meant to involve all employees by a fair understanding of QM to perform their job in the way proposed in QMS. Training and learning are considered as key ongoing processes in support of

organizational growth and advancement. Quality experts universally agree that training of top management, white collar and blue collar employees enhances the chances of success in implementing a QM strategy [188]. For implementation of QM in an industrial context, we focus our efforts in understanding the role and impact of three distinct processes: quality integration, use of QM in everyday use and evaluation of QM on regular basis for seeking room for improvements (presented in chapter six, seven, eight and nine). Evaluation of performance methods should be supportive of the improvement and change efforts of the organization in implementing QM [188]. When a QM is implemented, there is need to change the organization working style according to the adopted standard (*i.e.* ISO standard). For this purpose, there is a need to communicate and to instill the strategy for change to all employees about the QMI. There is a need of continuous and timely training for employees to avoid the impression that QM is the fad of the organization. QMI is about change and the change does not just happen. The change process is required to be communicated to all employees in order to make people understand why they are expected to be the part of the proposed change process [180] [375]. In this case, there is a twofold challenge in QMI. At first, we are going to destabilize the system with the help of change, and second to maintain and manage the change process in such a way that help employees to integrate in the QM system. In the change process, there is a necessity of change to adapt with the QM and at the same time, there is continuity to make the change successful as interplay of certitude and incertitude between employees and top management.

A model describing QM standard is a simplified representation *i.e.* ISO 9000 proposes required QM documentation – explained in chapter four, but a QM model do not explicitly explain how to implement the QM that makes it a naïve approach to management. This thesis provides a QMI approach to implement QM in industry. In this thesis we observe and examine several key relationships that are thought to be associated with QM implementation success. The concept of quality awareness is explained in chapter nine when modeling QM implementation. This is one of the major issues in all industries working that want to take on the quality challenges irrespective of their type of work. Quality awareness is influenced by communication-to-inform process (presented in chapter

2). Many of the middle managers have only a vague knowledge of the meanings of the term and associated values. Top management needs to understand which elements are necessary to develop the quality culture (explained in chapter 2) [73].

1.3.1 Research objective

This research intends to contribute to the understanding of implementing QM by creating a definition, grounded in the established fields of QM to integrate contemporary models of QM and the role of communication. In addition, this research seeks to develop a QM implementation model and to provide directions for future research. Based on the QM elements and implementation for the industry, this research aims at achieving the following objective:

- To obtain a QM implementation model for the industry.

In this way, relevant knowledge related to QMI for the industry can be put forward. In this research, many constructs incorporate elements from earlier studies and literature have been improved with new elements drawn from the academic and practitioners' literature. The QM evolves continuously and it is hoped that this present work captures major developments in the fields of quality.

Based on the research objectives, an extensive literature review (see below), brainstorming sessions with the author's promoters, and long discussions with quality practitioners, conceptual framework was proposed. The conceptual framework included a study of communication in organizations (presented in chapter two), quality management (presented in chapter three), ISO quality standard (presented in chapter four), computerized system validation (presented in chapter five), to observe and understand QM in industry. With the help of the conceptual framework, a QM implementation study was carried out.

I used an extensive bibliography presented in chapters two, three, four and five to extract useful elements that were developed to measure the model. Reviewing existing literature aims to integrate the elements underlying quality practices in a conceptual framework. Since all the quality elements were supported by various researchers (mentioned in chapter two, three, four and five), I was able

to use these elements in my industrial research. For industrial practitioners, this research should offer new paths for QM implementation process. The explanation is reported in the case studies (chapter six, seven and eight), where the QM elements and implementation is analyzed in organizations. I attempt to understand the implications of quality management implementation (QMI) process in the industry.

1.4 Scope and delimitation of the thesis

Among the major issues, one was to learn more about practical elements for QM and phases of QM implementation that can ease organization to plan and implement QMS. Our study consists of five elements of QM along with communication-to-inform process elements to implement QM. I present quality elements with communication-to-inform process in the same structure for convenience.

1.4.1 QM Elements

1. Top management
2. Employee's training
3. Customer focus
4. Strategic quality planning
5. Process management
6. Communication-to-inform process

1.4.2 QM implementation

We move forward with these quality constructs to fully implement QM. Customer orientation was treated in the next process in the customer context. The reason behind excluding customer focus from our study can be explained as very fewer departments have external customers in the industry.

- 1- Quality integration
- 2- Quality in everyday use
- 3- Quality system evaluation

QM potential gains are not achieved due to the failure of managing the change initiative. Our proposed approach of QMI can and should facilitate the change process. QM inevitably requires a change initiative process and awareness about the QMS during implementation phases.

1.4.3 Relevance of this Research

This study is one of the first attempts to observe QM practices and implementation in the industry that uses case studies of the automobile and pharmaceutical industries. Although most studies about QM have dealt with major elements of quality, including various studies related to ISO certification and / or QM implementation, however, there is little study about the QM implementation associated to quality awareness. No published study has used a QMI (quality management implementation) in the automobile and pharmaceutical industries. Therefore, the results of the above studies are not comparable with the results of our study. Research on QMI in industry will add to knowledge of QM and could help to develop a model for QMI.

Moreover, any comparison of QM practices in automobile and pharmaceutical industries in France can explore the relevance between QM model implementation and associated practices. From the QM organizational culture perspective, there is relevance between the practice of QM and organizational quality culture. This study helps to observe QM practices and allows a better understanding of these QM practices in different industrial environments (engine assembly line, computerized system, engine test bench,) when having to implement QM. Due to the accessibility to these organizations in different periods, and their commitment for quality, *Toyota Motor Manufacturing France*, *Sanofi Pasteur* and *Volvo Powertrain* were selected for the case studies.

1.5 Research strategy

For conducting industrial research, the data collection can be either qualitative or quantitative with pros and cons. The first allows studying selected issues in depth and detail with major advantages for production of rich and detailed information about a very small sample. In general, this method is oriented towards interpretation of valuable cases and inter-subjective construction of meanings rather than control and prediction [374], environment and situations under consideration and reduces generalization [280]. Whereas the latter applies formalized instruments to fit experience and perspective of a limited total of data collection. The biggest advantage of the latter method is to evaluate the reactions of a large sample against a defined number of questions, therefore facilitating comparison and statistical aggregation of the data [402]. A possible way out to annul the respective disadvantages of both methods is to blend a combination of both qualitative and quantitative methods. We followed a semi-qualitative approach for our research by taking into account the blend of both methods.

Any research strategies for a study can be linked to various factors including types of research questions being asked [397]; researcher's grip on *de facto* behavioral events; focus on present issues instead of past and historical phenomena [402]. Based on the objectives and research problem proposed in this industrial research study were the research strategies of a literature review, informal discussions with quality experts and team members, and industrial case study. The explanations for adopting such research strategies are presented in the following subsections.

1.5.1 Literature review

In the process of studying the QM implementation process and communication in the industry, various things were discovered including QM elements, ISO quality standard and certification, phases of the QM implementation that were descriptive in nature. Usually, descriptive studies make complicated things understandable through gathering, collecting, organizing and resuming information [260]. A literature review approach was first used to understand the

above notions. This approach is helpful in offering an elaborated understanding of the state of art of QM and communication in organizations. The literature reviewed described in this dissertation identified the key concept of QM and communication in organizations. Likewise, the literature review on various aspects of ISO standards covered the importance of ISO certification in the industry. Similarly, the literature review on QM practices and implementation phases is discussed briefly in various aspects. Similarly, the literature review on Computerized System Validation (CSV) demonstrated the importance of validating a computerized system. In this way, elements of the QMS and were explored for implementation.

1.5.2 Informal discussions and observations

In studying the implementation process of QM in industry and observing the effects of the QM elements on a QM standard (*i.e.* ISO: 9001) in industry, help of a literature review was obtained in order to improve our understanding. In order to discover more, it was decided that the strategy of informal discussions and observations would be used to obtain information on the areas identified for the research after reviewing the extensive literature. Communication-to-inform process to get a picture of the organization's practices is affected by the relationship established between both parties (respondent and researcher). A familiar conversation style plays an important role to access the appropriate piece of information and facilitates the communication process. Informal discussions and observations could obtain basic, elaborated information on QM elements and QM implementation from a number of members within an organization in a relatively short time period as compared to the formal discussions or structured interviews. Such information obtained from informal discussions was used to improve the QM implementation model presented in this chapter and make it more robust as we also studied the extensive literature existing on QM. Informal discussions can obtain some information, however, the discussions need a quick taking down of notes after the completion of each informal discussion session in order to memorize and recall a maximum of information under discussion. Observations were with the motive to understand employee's views and status that in turn can reduce the possibility of bias proposed by top management or misinformation [9]. Various

hurdles exist in an observation method and that is why research results can be refined with the help of various observations to collect qualitative data from a variety of sources. To observe the QM elements and QM implementation process, the case study approach was found helpful to explore various aspects.

1.5.3 Industrial case studies

I preferred to work directly instead of taking my research results from other tools (questionnaire survey, etc.) because I considered a case study approach more important to know what is happening in the industry and how the implementation can be studied while remaining very close to the working departments in the organizations chosen for my case studies (*i.e.* engine assembly line, quality and validation department, maintenance department). This choice was adopted after a careful review of the literature.

Typically, a case study is defined as a “‘bounded system’, a “single instance” according to Schostak [320]. He goes on to explain that a case study is constructed by elaborating and generating boundaries that emerge under given circumstances [320]. This includes understanding the change of events, and of relationships between the actors involved from different viewpoints.

A key challenge of case studies, however, is how one forms qualified generalizations or connections with other cases based on individual contexts? As a response to this, Schostak suggests the strategy of multi-site case studies that have common elements for analysis when comparing and contrasting the data.

The case study, then, cannot simplistically be reduced to being a single instance without reference either to others from which it is different or to a whole/totality/universal to which it has some generalizable relation [320].

The case study is common practice for QM to observe, test, validate, and refine QM studies. Though like every instrument it has several limitations in that it is influenced by personal opinion and other inevitable bias while analyzing the results to support the study. However, these disadvantages can be found in other instruments, *i.e.* questionnaires are used to obtain a big database of information

with a low level of details. No doubt, this research strategy is not without a number of shortcomings (lack of statistical proofs from research findings, personal influence on the phenomenon under study of research, etc). This strategy has unique advantages that allow an in-depth insight into the processes going on within complex organizations [402]. This strategy enables a researcher to deal with a broad range of evidence (documents, artifacts, observations, discussions, etc.) [397]. With the help of case studies, a QM implementation model was presented in chapter nine. These case studies can offer a clear understanding of the model and can be helpful for implementing QM elements in industry.

The case studies were considered suitable in world class automobile industries working in France to study the implementation process of QM, and to observe the effects of QM elements and implementation in industry. The engine assembly line, computerized system and engine test bench case studies for investigating QM practices seem appropriate for four main reasons. First, an engine assembly line is usually considered as the heart of the automobile industry. Second, a computerized system validation is compulsory for regulatory audits in the pharmaceutical industry (explained in chapter five). Third, validation of computerized system and linking it to quality models is important in terms of adding the compliance factor into QM. Finally, the test bench is extremely important for the performance and durability of engines, so the case study was found equally important to develop a model presented in chapter nine.

1.5.3.1 Case study questions

In this study, a QM implementation model has been developed on the basis of existing QM knowledge from experts, a literature survey, informal discussions in industry and case studies observations. The case studies can offer a real example to study QMI in industry. It should be stated that the case studies for implementation of ISO standard involve two organizations (case study one and three) and one for validation of a computerized system (case study two). The case study organizations were used to observe the implementation process of the QM implementation. I worked with the industry departments, participated in quality projects and observed QM elements and implementation phases and then used all of the above elements to develop this model. The model can be used to access,

compare and evaluate the organization's QM implementation practices through providing support in evaluating the organization's QM implementation. Moreover, I formulated an improvement plan in these case studies that were accepted by the organization's top management, so it could be inferred that the QM implementation model developed in this thesis is applicable in practice.

In this way, the weaknesses of QM implementation in the organization would be distinguished. An improvement plan could be brought into practice after identifying the weaker areas. However, it is top management who decides to accept the formulated improvement plan. This plan would be based on the possibilities of improvement from weaker areas. Zhang et al, 2001 mentioned that three points should be considered for conducting a case study for QM implementation [402] these include: (strengths of the organization's current QM implementation; weaknesses of the organization's current QM implementation; improvement plan to improve the organization's QM implementation). In case studies, we considered these phases by identifying the weaknesses of the organization's current QM implementation and then improvement plans were proposed. The objective of identifying weaker areas could be seen as an opportunity to look for improvements thus leading to improving an organization's QM implementation. The formulation of an improvement plan should be based on the organization's current situation (resources, objective, etc.) and commitment to follow quality awareness (implementation phases of the proposed model). Thus based on the above points, the improvement areas were identified and proposed.

1.5.3.2 Case study selection

In selecting case study organizations, various factors should be considered. The case study organization should be aware of QM implementation and its experience with implementation time should be at least two to three years. The experience of QM implementation is necessary as it could be significant in observing current implementation practices. In addition, the organization should have a minimum quality culture level. Furthermore, the organization should play a collaborative role in terms of working together to provide related information. Likewise, a world class organization with QM structure should be an excellent

opportunity for conducting the case study. Details about the case organizations are presented in the chapter six, seven and eight.

1.5.3.3 Data Collection

The major evidences for the research presented in this dissertation were collected in several ways. *i.e.* observations (direct - in organization; and indirect - hypothesis and theoretical analysis, theory refining,...), archives (organizational notes, training, presentation material, audits reports and records,...), informal discussions (open-ended questions and discussions with operation, quality and workshop management, supervisors, auditors and operators, etc.) with keen interest and involvement while working with the case study organizations. A collection of multiple and complementary data collection methods provided a comprehensive insight in the industrial research.

1.6 Thesis Structure

The thesis is divided into four sections. These are study framework, conceptual framework, case studies and QMI modeling.

- **Section one is the study framework that includes chapter one.**

Chapter one provides a brief description of the research, including its purpose and its significance.

- **Section two is conceptual framework that includes chapter two, three, four and five.**

Chapter two describes communication in organizations and discusses its role in QM. Explanation of communication in organizations is presented to address the internal and external communication issues in the organizations. Link between communication and QM is described to present the concept of communication in organizations.

Chapter three describes the concept of QM based on an extensive literature survey in the field of QM. The concept of QM is presented.

Chapter four describes the concept of ISO based on an extensive literature survey. ISO approach towards QM is discussed in order to establish the relationship between quality and management. The approach of ISO standards is presented.

Chapter five describes the concept of computerized system validation (CSV) based on an extensive literature survey. The CSV approach for pharmaceutical industry is discussed in order to present the concept.

- **Section three is the case studies that includes chapter six, seven and eight.**

Chapter six, seven and eight provide details about the industrial case studies. For these case studies, *Toyota Motor Manufacturing France*, *Sanofi Pasteur* and *Volvo Powertrain* were selected respectively. Each chapter explains the research strategies adopted including the case study organization description and its processes, the evaluation of QMI, key elements and improvement plans after evaluation. The conclusion and limitation of each case study are also presented. The case study approach provides an example of assessing, observing and understanding the QMI process in industry.

- **Section four is QMI Modeling that includes chapter nine.**

Chapter nine identifies the quality elements of QM to answer the research objective. Based on the literature review, three industrial case studies, a model of QMI is developed for industry. Finally, this chapter describes how to coordinate the model.

Chapter ten presents a brief summary of the research and the main conclusions with respect to the new knowledge derived from this research. The limitations of the research and issues requiring further study are also addressed.

2 Communication in organizations

2.1 Introduction

Based on the research objective and purpose discussed in chapter one, this thesis focuses mainly on the four concepts *i.e.* communication, quality management and organizational adopted quality standards and its implementation in organizations. In this chapter, we present communication in organizations. Section 2.2 describes communication in organizations including internal and external communication. Section 2.3 discusses the communication aspects with QM and the communication-to-inform process. The organizational culture is presented in Section 2.4. Section 2.5 summarizes this chapter.

2.2 Communication in Organizations

Organizational communication as a field of study and intervention has grown tremendously since the second half of the 20th century. Communication is a strategic instrument of great importance for any industry. In the global business environment in which the organizations operate, effective communications are essential if organizations are to realize their vision, reach their strategic quality objectives and strengthen confidence in their brands. Communication is present in every scope of human activities, and generally speaking in all living activities. It is impossible not to communicate [372] and everyone communicates all the time [17]. One can embed communication in the larger picture of information flow. Communication is a special type of information flow between agents. Indeed, it is the type of flow that language makes relatively easy to accomplish, but that is not exclusive to language [279]. According to Watzlawick et al. (1967), one cannot not communicate [373]. The “impossibility of not communicating” is dictated by the logic of the theory. Since the theory states that all behavior is communication, and one cannot not behave, which follows that one cannot not communicate [373]. Silence as absence of communication is itself a form of communication. Communication is a two way effort, involving the transmission of information and understanding from one person or group to another through the use of common symbols [364].

Communication in organizations is a general phenomenon influenced by industrial environments and the technical realities of information. People who

manage technology and all other resources in the organization are highly influenced by personnel training for a better integration and usage of QMS. Communication of organizations includes all techniques and technologies of social management [245]. Communication should address the issue of what the organization wants to accomplish and all information should be presented in order to make it clear to everyone working to participate in the accomplishment of common objectives [180]. Communication can be perceived in explicit and implicit forms of communication in organizations [203]. Communication has a dual function including leading an organization towards order through integrating communication and leading towards a form of functional disorder and dissipating communication in time of coping with crisis [17]. The biggest job of top management in managing organization is linked to communication [253]. Without the right communications planning, in parallel with organizational QM implementation plan, the organization's efforts will be short-lived [180].

Organizational communication is the flow of information (the exchange and transmission of information) within the organization [189] or the flow of messages within a network of interdependent relationships [137]. Goldhaber (1999) provided the definition of internal communication as “the flow of messages within a network of interdependent relationships”. [137]. While discussing the literature and history of internal communication [295], Putnam stated that the early work in this domain was forged by corporate concerns and interests and industrial communication from the 1920s to the 1950s, and in human relations from the 1950s to the mid 1970s [192]. In the 1960s-1970s period, two dominating factors were observed including the skills that made individuals more effective communicators on the job and the factors that characterized system-wide communication effectiveness [302]. In this period, internal communication focused also on psychological studies (superior-subordinate interaction, communication climate and information processing) and sociological studies (team group coordination, communication network, and usage of new technology) [295].

Kim (2005) discusses the distinctions between organizational communications types *i.e.* horizontal and vertical [192]. According to Kim, “horizontal communication relates to the informal interpersonal and socio-

emotional interaction with close colleagues and others in the organization who are at the same level”. Vertical communication is described as “job-related communication up and down the organizational hierarchy and may range from employees receiving information about the organization’s strategy to the ability for giving bottom-up feedback and advice to management” [192] [250] [251]. Vertical communication plays an important role in completion of tasks [251]. Some scholars explained communication is cultural specific [334]. According to Le Moëne, organizations are involved with cultural environment while adapting to it according to the internationalization and by maintaining the effectiveness of the organization [211]. According to Cerkevic, there are three major steps of communication. Launch the process, make it live, make it durable and perpetual [62].

The messages organizations communicate should be provided in a timely way and the communication should be truthful, open and relevant – in difficult situations as well as favorable ones. Whenever possible, organizations should stress their corporate values. The communications program should be planned and, where important issues are involved, coordinated to ensure that relevant information reaches the appropriate stakeholders at the right time. Organizations must seek to stimulate both “horizontal” and “feedback” internal communications. Communication can be divided into four stages: Identify and analyze the existing communication (audit), identify the strategy and plan an action, implement it and evaluate the results and react accordingly [62]. The audit should consider all quality aspects required by the organization (environment, quality values, interaction between top management and people, etc.)

Communicative top management: It is the responsibility of top management and each manager to provide context and motivate employees and to participate in this dialogue for organizational social cohesion [253]. Top management requires active communication – listening, motivating, explaining decisions, and asking for feedback. Managers should always communicate and all communications in the organizations should be prompt, relevant and consistent. One can communicate through behaviors in different situations. For example, a manager who keeps the

door of his office closed conveys a message that he does not want to see anybody at that time and or need not to be disturbed at that moment [254].

Relevant: Organizations need to focus their communications on important situations and facts that concern the recipients of the information; organization may avoid unessential information. Unessential information can create difficulty in understanding the desired message. Top management communication should be generally coherent with no contradiction because a paradox can lead to the situation of incertitude of questioning an existing situation in the organization. But, the incertitude can further lead to rendering dysfunctional attitudes in doing the job. Various surveys demonstrate that employees are affected by the communication of top management and their actions. If there is a difference between a spoken statement and actions, it can lead to a strong negative impact [254]. Information should be provided to all parties involved in a timely way in accordance with the organization rules. Organizations with basic messages must be coherent, regardless of whether they communicate internally or externally. Organizations should show the greatest possible openness in their communications.

2.2.1 Internal communication

According to Grunig et al. (2002), internal communication in an organization is a “specialized sub-discipline of communication sciences that examines how people communicate in organizations and the nature of effective communication systems in organizations” [140]. Internal communication in organizations may include actions of information and communication promoted by the management hierarchy, internal communications manager or department that is responsible for implementing communication policy of the organization. All these actions facilitate the observance by employees of organizational values and objectives. Internal communication facilitates team work and allows teams to find the way in which an organization launches its strategy [253]. According to March (1994), inconsistency in the interests of teams is at variance with the understanding of communication [227]. The information communicated by an organization internally should create a sense of identity for individual employees,

a feeling of unity with the organization and support of the organization's objectives. Internal communications primarily aim at promoting common values and understanding of the organization through an ongoing exchange. To motivate employees to proactively participate in this exchange, management should improve the utilization of information and feedback to achieve common goals and objectives. In a communication process, feedback between a speaker and a listener is important in order to determine if the message has been well conveyed [364] and top management is responsible to convey the message to employees [401]. Delay or absence of feedback can be a severe hurdle in the communication process in form of negative influence on satisfaction [35]. Absence of communication by top management with employees during major modifications of strategy creates difficulties by a massive rejection by the employees [41]. Thus, top management is required to integrate communication at the decisional levels.

Dialogue: Dialogue is an exchange of ideas between people in different units and different levels of the organization will enable each employee to become engaged in the organizational common values and its culture. Strategic dialogue and visible leadership promote a need for information and stimulate interest in the context of an organization's business. It is the responsibility of management and employees to proactively participate in the dialogue. Dialogue is the priority not only face-to-face, but also via electronic media. Making sense of information can be lost or be less effective in a conversation with some employees if the communication is not done in the form of dialogue. In keeping dialogue, top management must focus on communication to present to its employees. The leader must try to put the message into a relevant context and initiate a discussion on the consequences for the working group, on actions to be taken and on how to follow them up.

Many different information channels are available to employees who seek facts about the organization and its operations – the organization's intranet being one very important channel. Organizations are increasing the use of electronic media. New information technologies have redefined the group collaboration definition where everyone is at same distance *i.e.* accessible through network at an

instant [253]. Internal information and communication should meet all organizational needs.

As human beings in a social context, employees have a need for different types of information and communication. Each of following types of information is important for the employee's work motivation, business understanding, and sense of security in their role:

- Information relating to individual needs. (For example: personal development, competence development and career planning.)
- Information relating to jobs. (For example: work instructions, performance feedback and follow-up.)
- Information relating to the organization's situation. (For example: information about new customers, contracts, products, performance, financial results, etc.)
- Information relating to objectives and values. (For example: mission and vision, business objectives, strategies and plans, team goals and individual goals.)
- Information relating to the world in which the organization is operating. (For example: market trends, competitive situation, political decisions that affect business, etc.)

The leaders thus have a crucial communication role. The atmosphere in a unit benefits from an appropriate balance between these types of information.

2.2.1.1 Communication through intranet

The intranet of an organization is a communication channel for publishing information for all employees, and information targeted or useful for the employees of an organization, project, process or network. Confidential information should not be displayed on the general intranet. Such information may only be published on sites with access control.

Design and structure: In order to enhance the impact of internal communications on the intranet, the design and navigation structure should support transparency and communications within the organization. The design and navigation structure of websites must be consistent with identity rules and cognitive design guidelines [163] [164].

Access to the intranet: Information made available on the intranet of the organization is primarily intended for the use of the organization's employees. Contracted partners working on the organization's premises may, however, get access to web information, while access from partner companies residing in other networks must always have a controlled access.

Effective internal communications impact on productivity. Some aspects of internal communications share information, feedback and follow-up. It is also important to measure and follow-up the effectiveness of communication activities conducted by the organization's internal communications departments.

2.2.2 External communication

External communication includes all types of communications (public relations, sponsoring or lobbying, etc) that adds value to an organization and reflects a better image of its products or brand [253]. External communications support business operations by contributing to an enhanced knowledge about the organization and its products, by strengthening the organization's products, and by creating understanding of their efforts on the part of customers, shareholders and society. Non-verbal communication helps to provide the context for spoken communication [348].

To be successful, organizations direct their information to all stakeholders in different arenas. The communication should be consistent and long term, and the message should be adapted to suit the individual arena. In this way, organizations can reduce misunderstandings and create optimal conditions for their communications to be accepted and lead to desired results.

Taking the initiative in dealing with stakeholders and issues that impact on an organization image is a recommended strategy. This requires that an organization be responsive to the perspectives of the market and society. Continuous monitoring of the stock market, public opinion, legislation and customer preferences will facilitate proactive communications. Organizations operating globally should be perceived as having a single voice. Training and people involvement significantly rely on cooperation of the actors engaged in the process and are part of the production process.

An interesting issue in QM model and implementation is communication-to-inform process in organizations. In other words, how to improve the process of gaining information targeted to employees' objectives to achieve organizational goals and committed use to communicate with top management. Another issue in this thesis was quality elements for improved communication *i.e.*, people are always affected by awareness in organizations and thus influencing the most critical success factors in QMS. Although the main outcome of the research is not a new set of critical success factors, however, it responds to the call for more research in QM. An overview of existing literature and frameworks on QMS combined with this study considers organizational QM model along with awareness and communication-to-inform process thus making it possible to link with the information and communication sciences to the existing theories on QM.

2.3 Role of communication in QM

QMS systematically developed by and in organizations, generally aims at ensuring the stability, conformance and reliability of the product that meets the specified requirements. In order to do so, organizations are required to better define the production system, the tasks to be performed as well as the interaction of all quality elements. These processes are in fact based on the QMS that considers flow of information and its communication as an instrument that has to ensure the smooth running of the organization. Today, organizations deal with huge amount of information and a large number of communications is an important part of the strategy of an organization for achieving corporate goals. The outcomes of effective communication often reflect the manner in which the employees plan and manage the organizational tasks.

Top management and employees are in constant interaction with each other to implement the QM in organization with the help of communication and information exchanged. The position of communication is important in the successful implementation of QM. It provides the baseline to explain, to lead, to stimulate, to reassure, to make the suggestions coherent and constantly encourage employees and top management so that the QM implementation becomes systematic. Without this, the QMS cannot be effective and visible. A problem of work management is not independent from communication in the organization [255] where all the actors of the organization are required to participate and interact with information and communication.

The role of communication is frequently ignored in QM programs despite the concrete importance of group communication, team based problem solving and suggestion system (explained in the case study 3 - section 8.9.9). Relatively little research is done in observing the role of communicational issues in QM while exploring quality problems. In theoretical and empirical research articles, the discussion of the QM within organization are almost nonexistent [11] and very few articles focusing on communication theory in the organization are available *i.e.* [11] [110] [111] [378]. According to Allen & Brady, most of the practitioner-oriented authors of QM books readily acknowledge the importance of communication and very little academic study is available until now [11]. Understanding communication is important in the development of organizational quality initiatives [374]. Communication seems to be fundamental in the development of QM and its successful implementation. Communication plays a vital role in quality movement and in articulating problems, to the constitution of action plans and judgments made about problem analysis and decision making [147]. Effective communication has consistently remained among the top issue facing top management over the past many years [374]. The most important factor of success in a communication plan is the conviction and powers of persuasion of every member of management [180]. Communication is considered as among the most important tools of QM that allows employees to accomplish their tasks effectively and efficiently. In production, normally most employees depend on each other to communicate to ensure the effective flow of information. Organizational practices and standards to comply with objectives cannot be

successfully carried out in the absence of adequate communication [196]. Communication has a major effect on the realization of QM and quality assurance [17]. The impact of the quality of communication is an influential factor in QMS implementation steps. The employees of an organization, in particular, those who are directly engaged with clients directly must acquire a rich know-how and require necessary skills in communication [62]. ISO standards ask top management to adapt all necessary measures for an effective interaction between the clients and the organization [168].

Webb mentioned that an operation manager at *Communication Equipment* claimed “communication” remained the big problem. Similar statements were made by *U.S. Motors* quality supervisor that communication was the most difficult thing. Everyone wants to be in the communication loop [374].

2.3.1 Communication-to-inform process for employee’s awareness

Communications is a strategic instrument of great importance for quality. Information about the progress of quality improvements and achievement actions should be continually supplied to all employees [80]. Communication aims at promoting common values and business understanding through an ongoing dialogue. Communication plays a vital role from clear quality policy until implementation actions to achieve goals. Effective communication between the workers and managers helps create a streamlined process that is essential for a QM. Under its communication function, management performs its assigned tasks so that everybody can follow SOP – Standard operating Procedure (explained in case study three – chapter eight). Management involvement will make sure job descriptions are completely aligned with the organization’s needs. Constant efforts are necessary to improve communication activities directed towards maintaining current technological, managerial, and operating standards. Middle management must spend time for discussion on quality with different team members to get them involved. Communication is the way to be reminded of the cultural environment as it is also the way to get out of it and to re-produce and to re-generate a new

universe of making sense of relevant information. Communication links up and encourages QM adoption [379].

Information and analysis is measured in terms of availability of quality related data, timeliness of quality related data, and usage of quality related data at all levels in the organization [119] [299]. Researchers conclude that management theorists see information processing as useful in general but potentially irrelevant or even hazardous in specific situations [83]. Information from all sources of organization (workers, agents, vendors, and customers) is also important for improving and sustaining quality processes, products and services [75] [97] [167] [175]. Top management can be more effective only if they get the information they need to evaluate, decide, and implement the appropriate course of action for their business [274]. Studies emphasize the key roles that information and information technology play in QM [280] [329].

Information sharing refers to the extent to which critical and proprietary information is communicated to all concerning parties. To improve information usefulness, the importance of timely, reliable, and adequate information has also been noted [100] [128] [318]. Flow of information within the organization is among the critical strategies for successful QM programs [358]. A major implementation issue of QM in the industries is the need to collect data and carry out analysis on them. The success of a QM program also depends on the use of information technology. If properly planned and implemented, it can greatly enhance the application of QM in the organization [23]. Maintenance of quality requires continuous flow of accurate information about processes that generate an organization's products [299] [238].

Getting the relevant information from all phases of an organization's operations and using it to monitor and improve quality remains the fundamental part of QM. QM stresses decision making based on facts involving analysis of information (about customer needs, operational problems, and the success of improvement attempts). The Baldrige Awards explains this factor as "scope, management, and use of data and information to maintain a customer focus, to drive quality excellence, and to improve performance" [313]. It recognizes the importance of integrating information from inside and outside the information

system (e.g. suppliers, customers, competitors) [5]. Mellat Parast refers quality information availability to the availability of quality information for effective and efficient QM practices [300] that helps top management in making decisions [238].

Chang (1989) [385] and Ross (1991) [403] proposed processes for integrating quality information systems with market research, product design, product planning, process and production management, and QM. Similarly, Water and Vries (1992) suggested an integrated information system to determine quality policies and assist other functions set up and implement quality plans [407]. Various researchers [318] [343] [18] presented frameworks from manufacturing perspective to incorporate quality-related information into the manufacturing functions of pre-production, production, and post-production phases [5].

It is not what you say but how you say it. To implement QM we need to avoid communication-not-to-inform approach. Communicate without informing builds barriers to communicate-to-inform process and create confusion, misunderstanding about the quality system. A message is not communicated unless it is understood by the receiver. Communicate-to-inform process is an exchange of information at the appropriate moment with the appropriate person about an appropriate subject matter [205]. Communication-not-to-inform, however, is an exchange of information without appropriate and contextualized interaction. This can take the form of, for example, an exchange of information at an inappropriate moment, or with the inappropriate person about an inappropriate subject matter. Communicate without informing blocks transmission of information, explanation, quality instructions and procedures of a quality management system. The quality department is required to seek feedback in a supportive way after all communication to reduce the chances of misunderstanding. By using communication-to-inform skills, a quality manager or quality department manages to organize and control QM standard deployment by informing about QM. Communication-to-inform activities involve in QM are helpful in co-coordinating with employees who are going to apply standards in their everyday corporate life. I believe that among other factors in QM failure is the misinterpretation of a QM standard, and a misunderstanding of change in employee's routine activities as the

result of a breakdown in communication. When communicating for QMI, it is important to understand and to be understood and this is communication-to-inform process where both parties – sender (quality department or QMI team) and receiver (an employee who will implement the standard) know how the other makes sense of relevant information and intent for quality standard to be deployed. Questioning is required to determine what the employee makes sense of and for this purpose quality department may get feedback to the communication by asking the employee in a friendly way what he or she understood. Feedback is important for quality department in order to create mutual understanding of quality standard implementation. Communication to inform is the glue that holds all quality elements in an organization together.

2.4 Organizational Culture

Organizational culture is not homogenous, uniform, standardized or static [189]. It evolves with the passage of time and it appears reasonable to state that the cultural system will exhibit continuous, incremental changes punctuated on occasion by more periodic, radical changes [371] [374]. According to Dixon (1999) organizational culture is “the set of collective meaning structures that organizational members use to interpret the nature of their world and themselves in relation to it. They are assumptions that are so fundamental that they are for the most part tacit” [90].

Culture can be characterized as the common set of values, social ideas, attitudes, norms or beliefs that members of organizations share [395]. Goodenough, one of the founders of cognitive anthropology provided the definition of culture as:

“As I see it, a society's culture consists of whatever it is one has to know or believe in order to operate in a manner acceptable to its members.... By this definition, we would note that culture is not a material phenomenon; it does not consist of things, people, behaviour, or emotions. It is rather an organisation of these things. It is the form of things that people have in mind, their models for perceiving, relating and otherwise interpreting them. As such, the things people say and do, their social arrangements and events, are products or by-products of

their culture – they apply it to the task of perceiving and dealing with their circumstances” [390].

In this context, the concept of culture is associated with a coherent system of identifying attitudes, values, and frames of activities linked to a given pattern of behaviour [403]. What defines a culture is not the presence or absence of a certain cultural trait, but rather the way in which it pursues its objectives in a given direction. One way of doing this is to provide a system of accepted rules and standards of behavior, in other words, a "code of ethical values" [395]. Our purpose was to examine by evaluation of QMS the degree to which the behavior that people indicate is appropriate according to the QM of the organization (what is they say they do according to the standard adopted by organization). We use Goodenough's definition of culture [390], and take as the context for this investigation the QM implementation.

Strong culture can be defined as norms and values, which have significant influence on employees' behaviour [197]. For an organization, strategic planning may lead to constitute a strong culture if organizational cultural values and norms match the organizational environment and strategy [180]. This definition has a broad meaning and represents various aspects of an organization and thus focuses on how it influences QMS. Nowinski et al. (2007) mentioned the Zammuto and Krakower's competing values framework which discussed four types of cultures that have three dimensions: focus on people versus the organization; preference for structure (stability and control versus flexibility), and emphasis on specific types of strategies and outcomes [399]. Nowinski et al. wrote that group cultures are people-oriented, based on flexibility and trust, and implementation occurs through consensus [399]. Developmental cultures also value flexibility, but the focus is on the organization, with an emphasis on growth and resource acquisition and a willingness to seize opportunities. Rational cultures are based on efficiency, uniformity, and goal achievement, and implementation is most likely approached through planning and goal-setting [266]. Hierarchical cultures are similar to the rational type in their emphasis on productivity, performance, stability, and procedures [266].

Two researchers observed and interviewed 5000 managers to establish the essential job of top managements in North America [39]. They came to the conclusion that top management is responsible for developing a sort of culture in the organization which helps the appropriate functioning of an organization. This culture is the complex combination of several formal and informal activities. Thus, the role of top management is to manage business and teams, motivate team, create innovation, develop competent teams to achieve targeted output by excellent participation from team members [255]. Schein (1985) highlighted the role of the leader in creating and managing organizational culture and suggested that, when a culture becomes dysfunctional as a result of change, it is the leader who must act to assist the group to unlearn some of its cultural assumptions and to learn alternative assumptions [319]. Increased competition, globalization, mergers, acquisitions, alliances, and various workforce developments have created a greater need for a strong culture. There is a clear consensus that QMS and associated practices must be built into the management style that operates the organization. The existing knowledge of QM requires a fundamental change in the way in which organizational members work together to meet customer requirements [180].

A strong association is required between employees' perceptions of organizational culture and communication [189]. The explanation and implication process which provide the basis of developing organizational values, norms, and expectations begin with communication [195]. Although all organizations have cultures, some appear to have stronger, more deeply rooted cultures than others. The strength of a culture refers to how strongly and deeply cultural assumptions are embedded into the everyday work of the employees [181]. There is also strong anecdotal support indicating that the primary cause of failure of most major change efforts (such as QM and reengineering) has been the failure to successfully change the organizational culture [55]. Culture promotes individual identification with the organization and its objectives [288]. Learning conforms to culture; the nature of learning and the way in which it occurs are determined by the organization's culture [104]. Cultural change helps employees to be aware of the change initiatives. Culture can be thus reinforced with an effective program of training and learning [288]. Details about employees learning is presented in next chapter (section 3.3.).

2.4.1 Communication, QM and Organizational Culture

A major problem faced by QM implementation is that what people say they do can be different from what they actually do. The question of implementation is influenced by the culture [310]. Brown and Starkey (1994) stated that the culture of an organization is an important factor affecting attitudes, and systems and processes pertaining to the management of information and communication [50]. Their study showed that culture configures and develops communication, which influences the nature of information (quality and quantity) distributed in the organization. Philip and Mckeown stated that “the above investigation provided an insight into the detrimental effect of a dominant culture, which produced a workforce that was unable and/or unwilling to foster a stable communication system throughout the organization” [287]. Communication from top management and other employees in an organization has been shown to be an important determinant of organizational culture [256] [308]. Changing the patterns of communication has effects on the culture of an organization. It is, thus, imperative to create and develop a culture that encourages communication and knowledge sharing, which will allow employees to see the whole in the part rather than taking a myopic stance [196]. The organizational structure delimits responsibilities and communication channels and can facilitate the flow and processing of information [122].

The study of QM from a cultural perspective is based on an understanding of the cultural dimension of quality. The focus is on understanding the role organizational culture plays in the QMI process. In this research field, organizational culture is assumed to be a major factor in inhibiting or supporting successful QM implementation. Hildebrandt’s research on quality culture and QM emphasized the importance of corporate culture and uncovering current underlying cultural assumptions as primary condition for successful QM implementation [150]. Various researchers provide analysis of organizational culture in research on QM [191] [223]. Organizational culture is among the current trends in prioritizing the direction and limits for organizational change [233]. Researchers point out if a strong QM culture is always advantageous for organizations in

forming strategic culture or it contributes only to one part in implementing QM [197]. An organizational culture may be affected differently by the introduction of a QM system, it may be more or less receptive to QM, and as a result QM implementation may have different outcomes within the organization. Researchers point out which type of culture is vital [84], and the effects of organizational culture on the successes and failures of QM implementation [191]. Organizational culture, affects both the kind and amount of communication amongst organizational members [196]. QM can serve as a conduit for communication if implemented in organizations, which is essential for organizations that embrace a quality-oriented culture.

2.5 Summary

This chapter started with defining communication in organizations. Internal and external communication in organizations is presented with the help of literature survey. Then role of communication in QM is described. Organizational culture is discussed in QM and communication context. Based on the above literature and case studies presented in chapters six, seven and eight, QMI (quality management implementation) model will be presented in chapter nine. Using the concept uncovered in the review of the literature, it was possible to explore how communication-to-inform process helps employees to understand QM and attach QM elements in an organization together, narrowing the focus to that of the research objective for this study, and then arriving at a model presented in chapter nine. In next chapter, we will explore the second key concept of our study – quality management in organizations.

3 QM in Organizations

3.1 Introduction

The purpose of this chapter is to give the reader a short description of quality management that aims to depict how QM literature identifies quality elements necessary to anticipate the QM activities within an organization. The overall purpose of the review in this chapter is to arrive at appropriate elements of QM in organizations. This chapter presents an extensive literature review of the QM in organizations and focuses on the identification of the QM elements. The purpose of this chapter is to provide a clear picture of QM definitions and components to narrow the focus of this study to this topic. Section 3.1 presents the introduction. Section 3.2 defines quality and QM approach in organizations. Section 3.3 describes the literature review of different quality elements used in this study. Finally, Section 3.4 summarizes the chapter.

3.2 QM approach for organizations

The design and implementation of an organization's QMS is always influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. An efficient QM requires quality actions to be planned, controlled and improved. Today, it is difficult to say that any industry is not facing a multitude of challenges either in terms of quality, cost, or material or people. However, giant companies acquire certain level of expertise and knowledge to run their business, which is sufficient to handle their projects in most cases.

Quality has been heralded as the source of competitive advantage during the 1980s and 1990s, particularly when Western companies began to see the loss of their market share to their Japanese competitors [293]. QM has been a popular intervention all around the world but particularly in industrialized countries [127] [83]. The QM movement was supported by Japanese companies, which gave to the theory a practical vision [313]. Several QM models are proposed [75] [87] [114] [167] [177]. In France, the quality foundation like AFCIQ (*Association française pour le contrôle industriel de la qualité* - 1957) and AFCERQ (*Association française des cercles de qualité* - 1981) played an important role in driving the quality movement of 1980s [377]. QM has been recognized as one of the key

strategies for organizations to improve their productivity and international competitiveness.

The term "quality management" has no single agreed definition, what is the exact or precise definition, what makes it successful, and how it should be implemented? Even the quality experts seemed to struggle to find just the right words to define the term. This might be due to the fact that the term "quality" means different things for different people [87] [142], which in turn may result in different models of QM. However, they share a common set of assumptions and prescriptions [142] that often seems to be in the form of TQM (see section 3.2.2), *Kaizen*, etc. that all fall within the QM approach.

3.2.1 Defining Quality

The term quality is often used in a vague way and no standard definition exists to define quality. There is no universal agreement on what the term "quality" means [402]. In general, quality can be specified as the ability of a product/service to fulfill the requirements and expectations defined by the customers and stakeholders - either internal clients (employees, management) or external clients (who want value for their money). In a broad sense, quality is anything that can be always improved [166]; fitness for purpose or use [176] [179] conformance to requirements [75], the customer's opinion [114] and/or uniformity about a correct target [87]. Quality is a measure of the performance as experienced by the customers. Excellence in product quality is not an end, but a starting point [404].

Defining quality is not easy. Quality has no fix definition and is often misunderstood. In daily life, the term "quality" is equivocally used and is often perceived as an immeasurable characteristic of a product that is difficult to manage or control. However, quality experts provide a series of measures to operationally define, measure, manage, and improve quality in all domains including products, processes and services. Quality is a dynamic issue that needs continuous improvement [166]. AFNOR (*association française de normalization*) defines quality as the degree to which a set of inherent characteristics fulfils requirements.

Similar definition is presented by ISO (ISO 9000:2005(E) [168]. The inherent characteristics can be of a process, an activity, an organization [63] and these requirements are defined by user [216].

Imai's definition [166] leads towards the continuous improvement process. Juran's definition [176] [179] implies that product requirements must be clearly stated and understood and that the conformance to requirements be continuously measured throughout the product development. The definition of Juran seems to be close with Crosby [75] in which customers' requirements and expectations are considered essential. Feigenbaum [114] and Deming [87] definitions explain that quality means different things to different people, depending on the task. Ultimately, the customer's definition of quality is the real one that matters. AFNOR and ISO's definition of quality embraces the former definitions and considers quality as integration of essential features and characteristics which determine the extent to which the product satisfies the customer requirements [216].

According to Mellat Parast (2006), some approaches towards quality refer to more internal aspects of quality (manufacturing-based approach, etc) there are others that consider more to external aspects of quality (user-based approach, etc), in this regard, a combination of above approaches including both aspects is helpful in developing organization-wide concept of quality [238]. We take advantage of co-existence of different approaches to develop our definition of quality management presented in the next section.

3.2.2 Defining Quality Management – QM

Reed et al. (1996) indicated there was no consensus on the definition for QM, since its definition varied based on the approach taken towards quality [304]. QM is a management concept that focuses on the collective efforts of all managers and employees on satisfying customer expectations by continually improving operations, management processes, and products [33]. QM can be defined as a holistic management philosophy that strives for continuous improvement in all the functions of an organization [190]. QM has been considered as a widely applied

process for improvements, but with mixed success [313]. The *European Foundation for Quality Management* [121] defines QM as “all manners in which an organization meets the needs and expectations of its customers, personnel, financial stakeholders and society in general”.

Researchers in the domain of QM argue that the final objective is to establish a management system and an organizational culture (define in previous chapter) that ensures customer satisfaction and continuous improvement [174] [333] [142] [290] [381] [190]. QM is a continuous process that aims at quality improvement in all processes and activities in the organization [240].

According to a research study that reviewed the three quality gurus' (Deming, Juran, and Ishikawa), the core elements of QM found were:

- 1- clear identification and measurement of customer requirements and needs;
- 2- use of functional teams to identify and solve quality problems; use of scientific methods to monitor performance and identify points of high leverage for performance improvement;
- 3- use of logical process management heuristics to enhance team effectiveness [142].

QM is "the agreed organization wide operating work structure, documented in effective, integrated technical and managerial procedures, for guiding the coordinated actions of the people, machines and information of the organization in the best and most practical ways to assure customer satisfaction and economical costs of quality" [114].

TQM is a continuous process of improvement for individuals, groups of people, and whole organizations; it encompasses a set of four principles (1. delight the customer, 2. management by facts, 3. people-based management, and 4. continuous improvement) and eight core concepts (1. customer satisfaction, 2. internal customers are real, 3. all work is process, 4. measurement, 5. teamwork, 6. people make quality, 7. continuous improvement cycle, and 8. prevention) [186]. Some researchers defined QM as an integrated approach to achieving and

sustaining high quality output, focusing on the maintenance and continuous improvement of processes and defect prevention at all levels and in all functions of the firm, in order to meet or exceed customer expectations [117].

QMS is an approach to management that can be defined by principles, practices, and techniques [83]. The major principles are customer focus, continuous improvement, and teamwork. Each principle is based on a set of practices like customer focus, process analysis, team skills training and supplier collaboration. The practices are deployed through a wide array of techniques like quality deployment function, control charts, six sigma, etc.

QMS denotes organization-wide quality, operationalized through top management, internal/external cooperation, effective process management, product design, learning, customer focus and involvement, employee fulfillment, and continuous improvement [11].

QM is a framework with the combination of management commitment, adopting the quality culture philosophy, being closer to customers, being closer to suppliers, benchmarking, training, open organization, employee empowerment, zero-defects mentality, flexible manufacturing, process improvement, and measurement [290]. QM is, thus, a management and organizational philosophy that emphasizes continual change in the quality and efficiency of the production system [171].

The definition of QM principle in ISO TC176 is "a comprehensive and fundamental rule or belief, for leading and operating an organization, aimed at continually improving performance over the long term by focusing on customers while addressing the needs of all stakeholders." [402].

Ghobadian and Gallear (2001) [135] suggested in the broader QM literature that QM has a dual make-up; a 'hard-side' and a 'soft-side', where the 'hard-side' focuses on systems, tools and techniques and on establishing standards of performance, and the 'soft-side' concerns attitudes and values reflecting the emphasis given to mobilizing all employees around the goal of continuous

improvement and enlisting their active commitment by means of participation and responsibility [385] [150] [309] [45].

In our case, the following definition of QM is considered because our QM model is based on these constructs to conduct case studies presented in this thesis. “A management approach for continuously improving the overall performance based on five core concepts top management, people (training and learning; involvement and participation), strategic quality planning, customer orientation and process management”. Moreover, three phases are used to implement QM that includes quality integration, everyday use of quality system and quality system evaluation for continuous improvement.

3.3 Literature Review

The theory of QM has been developed from three different areas. Contribution from quality experts (Deming, Crosby, Juran, Ishikawa, etc), formal evaluation models (*European quality award* (1988), *Malcolm Baldrige national quality award* (1987), *Deming quality award* (1951), *French quality award* (1992), etc. and measurement studies [317] Flynn. et al. 1994, etc.). Based on the literature presented in this section, I proceed to construct my QM features in order to analyze the QMS in the case studies presented in chapters six, seven and eight.

3.3.1 Top management

There is a shared agreement among quality experts and in quality literature about the decisive role played by top management in effective implementation of QM [87] [368]. QM advocates emphasize the activities of senior top management much like transformational top management [29]. Top management support is the major driver of QM, which significantly correlates with other QM practices [238].

Quality experts identify the critical role and responsibility of top management in quality improvements [87] [75] [177]. Management is responsible for goal setting and for creating and sustaining change as needed to remove deficiencies [176], and to reinforce quality values in their organizations [173] [174] [178] [220]. Primary responsibility of top management should be the

commitment to quality and willingness to support efforts necessary to achieve the goals [75]. Top management is the key architect of change that provides a sense of direction for the workers and for the organization [128]. Increased level of quality performance does not exist without strong top management commitment [129]. Peters identified top management as being central to the quality improvement process, discarding the word “management” for “leadership” [286]. According to Peter, the new role is of a facilitator, and the basis is “managing by walking about” (MBWA), enabling the leader to keep in touch with customers, innovation and people, the three main areas in the pursuit of excellence [286].

For continuous improvement, management commitment and vision to quality is crucial [283]. Top management committed to quality should not only be involved in QM and improvement process, but also strongly encourage employee involvement in QM and improvement process [402]. To implement QMS successfully, top management must be committed to the ethos of QMS principles [273]. Puffer and McCarthy (1996) provide a framework for top management in a QM context and argue that top management's ability to create a vision and promote change is at the heart of successful QM implementation [294]. The empirical research affirmed that top management is the major driver of QM implementation in an organization [386] [190] in achieving world-class levels of quality [31]. In the *Malcolm Baldrige* conceptual framework, top management support is the driver of the QM process in organizations [337] [386]. The *European Quality Award* (1994) considers the central and decisive role of top management in making the goals, values and systems that drive the performance improvement.

Literature survey on QM reflects that high commitment from top management is vital for the effectiveness of the QM. Lack of top management commitment is among the major reasons for the failure of QMS attempts [384] and seems to be the major obstacle in successfully implementing a productivity improvement project [152]. Skinner (1986) also addressed the management issue in the 1980s by attacking management's definition of productivity programs as results-oriented projects instead of process-oriented improvements [404]. Top management was accused of projecting a narrow vision of the organization [327]. The management is held responsible for planning and foreseeing problems about

wastes of manpower, materials, and machine-time, which raise the manufacturer's cost and price that the purchaser pay even if he is not willing to subsidize the waste [87] [377].

3.3.2 People

People are the most important element of quality system that participate, promote and make the quality system. It is important that top management realizes the different possibilities in involving people in quality awareness activities as a strategic issue, which in turn contributes to the organizational goals. This interaction can be achieved by linking the quality system and organizational learning. According to Endlich (2002), organizational learning are the activities that take place in an organization to acquire, create, and transfer knowledge that, over time, result in behavioral or procedural changes, as well as an increase in knowledge and understanding [388]. Two important factors can be translated as training and learning, and participation and involvement.

3.3.3 Training and Learning

Training is the systematic acquisition and development of the knowledge, skills, and attitudes required by employees to adequately perform a job or task or to improve performance in the work environment [138] [204]. Training forms a vital part of QMS and is viewed as key ongoing processes in support of organizational growth and advancement [75], [76]. Training provides a forum for communication of new organizational strategy, new values, new tools, and new ways of performing work [188]. Training and learning is important for continual updating and improvement, and top management is to provide these opportunities [87] [88]. Many research results reveal that training and learning is one of the most important elements in a successful implementation of QM [225], a single strategy to improve quality and productivity [173] [174] [212]. Training is the second most commonly used QM implementation practice in the United States [142]. Employee's training explains the level of continuous and intensive training

as an essential part of QM [69] [171]. Training indicates to the employees that the organization values train workers [188].

Training and learning involve a systematic approach [63] which requires systematically gathering data about the employees' or the organization's needs. The analysis includes several factors like the goals achieved by the organization, the learning requirements by the workforce to accomplish objectives, strengths and weakness of teams. According to numerous researchers, acquiring the high quality level depends on the excellent use of the talents and abilities of an organization's entire workforce [44] [69] [95] [134] [337]. Organizations that implement QM invest heavily in employee's training and learning programs at different levels [382] [386].

Ishikawa professed that the success of these quality circles is highly dependent on statistical quality tools in order to achieve the significant results in terms of productivity, quality improvements, safety and cost reduction [167]. He presented a set of seven basic tools of quality which are listed below:

Seven basic tools	
Pareto analysis	Which are the big problems?
Cause and effect diagrams (Ishikawa diagram or fish bone)	What causes the problems?
Stratification chart	How is the data made up?
Check sheets	How often it occurs or is done?
Histograms	What do overall variations look like?
Scatter charts	What are the relationships between factors?
Shewhart's control charts and graphs	Which variations to control and how?

Table 3-1: Seven basic quality tools of Ishikawa

Ishikawa (1985) recommends that employees receive training for the above seven basic quality tools [167]. Top management commitment is vital for employees' participation in quality activities and employee training and education

should focus on the quality issues [114]. Learning and training are one of the key elements of quality in which many people are involved, so the success of the implementation depends directly on how well they have been done [394]. Long term training is identified as critical factor for successful implementation of QM [389]. Several studies indicate that employer-provided training might increase productivity by as much as 16% if the training can be specifically applied to an employee's job [36]; [27]. Newsletter, poster slogan, etc are commonly used for training employees [402].

Crosby strongly rejected the idea that "error is inevitable" [76]. According to him mistakes are stimulated by a lack of knowledge and lack of attention. Appropriate training can remove the first and a self commitment towards excellence (zero defects) can heal the second [76]. Extensive research results reveal that education and training are one of the most important elements in a successful implementation of QM [402] [403] [404]. Training can move an organization beyond preventing errors to a point at which breakthrough achievements are realized [177]. In organizations pursuing towards excellent QM practices, employees receive 40 to 80 hours of training per year with training expenditures around 3-5% of the payroll [97].

QM training involves developing problem-solving skills that can be applied to continuously improving work processes and as outcomes increases the organization's capabilities and partially explains TQM's competitive advantage [155]. Workers gain knowledge and skills that enable them to do their jobs better and therefore be more productive [228]. Training is key element in QM to communicate the nature of change initiative and how to implement a QMS. The organization that views training as an ongoing process cultivates the learning behaviors in employees and managers that are necessary to successfully implement change [188]. Training on quality tools (*i.e.* statistical process control charts, FMECA, etc.) play an important role in facilitating QMI and there is a need to provide training on an ongoing basis. Statistical process control charts are described in chapter six and FMECA is presented in chapter eight while presenting case studies one and three respectively. Management must make sure that the training will be utilized in daily routine activities of employees to seek

implementation of QMS. Training plays an important role in encouraging employees to consider QM as a whole and to see how they function to implement QM.

3.3.4 Participation and involvement

Involvement means to empower employees, to give them information, increase their knowledge and reward quality performance [275]. Labour defined empowerment as “the feeling of being able to change and transform a situation via cooperative action” [200]. Lawler [207] [208] has also explored the issue of employee involvement via four elements of the organization as follows.

(1) Power. It refers to controlling the distributing situation of the decision rights of the organization, which is similar to democratization in the enterprise.

(2) Information. This means giving access in a certain way (or “form”) to issues of communication such as the employees’ rights and obligations in the organizations or transfer of knowledge.

(3) Knowledge (*savoir*, in French, as a socially constructed and codified phenomenon). This is major element, it is related to being able to make use of “appropriate information” that affects the employees’ skills, capacity and professional aptitudes.

(4) Reward. It is a significant element, which affects the efficiency of employee involvement. It is also the path for the employees to obtain power, information and knowledge.

This is to say that when properly managed and prepared, teamwork improves processes and produces results rapidly and in an efficient way through the free exchange of ideas, information, knowledge and data. Communication is central and the key to solve the problems, to the establishment of action plans and to the judgment about the problems analysis and responses [148].

Imai (1986) defined an organization as a combination of three blocks, hardware, software and human-ware [166]. Human-ware is the fundamental

building block of any QM. The exclusive point at which real responsibility can lie is with human-ware actually doing the job or accomplishing the process. Any process is less complicated than the control of any one individual, and the only effective and working way to improve or redesign process is via teamwork. Ishikawa urged organization-wide employee participation as the key to the successful implementation of QM. Participation is decisive in inspiring action on quality improvement [177]. Participation may contribute to the establishment of an organization-wide quality culture. Employees in organizations should be encouraged to report their work problems [402].

Employee involvement is the means to examine the operation of democratization in the enterprises, which not only decreases the obstacle of the system's operation, but also is the way to collect common consensus and pursue the benefits of most of the people [218]. It affects the achievements of the organization, while the enterprises are pursuing additional values since the employees' active participation in the process of decision will enhance their centripetal force in the organization as well as upgrade their working satisfaction [246]; [321]. Employee involvement relates to the involvement of employees in problem solving, and decision making at all levels in the organization [275].

It has been emphasized by Rao et al (1999) that employee involvement encompasses a range of policies that, at the very least, permits workers to suggest improvements and, at best, gives all employees the ability, motivation, and authority to improve continuously as to how the organization operates [239]. Shared understanding of job requirements and organizational objectives can be well coupled through effective organizational communication [420]. Both recognition and rewards have a powerful motivating effect on people at work. They enhance a person's awareness of self-worth and self-esteem [347]. Giving recognition and rewards are gestures that recognize a person's uniqueness and human dignity [25].

Teamwork is related to the two practices of internal support of employees by the organization, and work information exchange [131]). Teamwork emphasizes that the focus of all workforce is based on a common goal of quality rather than on intermediate goals that are advantageous for a particular organizational group only

[273] [317] [333]). In terms of work activities, teamwork compels information sharing among members, collaborative decision making, and agreement in the performance measures that are used to review the quality of work. Teamwork includes suppliers and customers along with employees [83]. QM literature identifies employee involvement, empowerment and team commitment as crucial elements of a successful QMS [46] [61]. The core of QM is involvement of all employees and their emphasis on continual change that is engaged and guided by, a clear and dedicated focus on serving customer needs [171].

The management literature tells us that teams are appropriate when there is a need for the coordination of activities, where work needs to be creative, or where major breakthroughs in performance are required [305]. In addition, research has shown that in addition to providing an innovative approach to solving production problems, cross-functional teams also can help reduce product development times [101]. Teamwork, as a principle of action of QM, can have positive effects on innovation by fomenting technical communication and information flows, so necessary in the formulation of innovation projects [283]. Ebrahimpour and Withers (1992) found that the firms that used QM demonstrated higher levels of worker involvement in the quality effort [99]. QM without employee's participation is like a body without soul [335].

QM practice broadens employees' roles by providing them with timely and accurate information [333]. SME's that have adopted TQM and are promoting QM programs which provide an active means for participation [146], often put problem solving and responsibility for quality back into people's hands, instead of giving it to management [384]. QM literature has associated cross-functional integration of quality efforts as an enabler of teamwork, cooperation, and quality-oriented culture [209] [206] [248].

3.3.5 Customer focus

An extensive literature survey reveals that the customer focus and satisfaction form the most heavily weighted category in QMS and quality awards [5]. Customer focus encompasses an organization's knowledge of its customers,

overall customer service system, responsiveness, and ability to meet customer requirements and expectations [67]. In a customer oriented organization, the focus is on customer requirements. In such organizations customers define quality and customers have the authority on quality [299]; in a customer-oriented organization, customer satisfaction drives all organization actions [91]. Consequently, the organization must look to its customers first in determining what it needs to do and in evaluating its success at doing it [337] [285]. Deming (1986) suggested that organizations realize what the customer needs and requirements today and in the future, so that products and services can be designed to satisfy those needs and requirements [87]. Ishikawa (1985) shifted the attention on quality to a customer focus, but extended the notion of a “customer” to include internal as well as external “consumers” of the previous stage of processing [167].

Customer focus is the underpinning principle in the QM and has the strongest significant predictors of operational performance [313]. The key to QM is sustaining a close relationship with the customer to fully understand and determine the customer’s needs, as well as to receive feedback on the extent to which those needs are being met [119] [402] in order to avoid quality problems once full production begins. Customer satisfaction may very well predict the future success or failure of a firm [394]. Companies such as *Chrysler*, *General Motors* and *Ford* established customer needs as a top priority and initiated aggressive QM programs [88].

Customer focus can be defined as the extent to which an organization continuously meets and exceeds customer needs and expectations. A flourishing organization recognizes the need to consider the customer first in all strategic and corporate decision. The key to QM is maintaining a close relationship with the customer in order to fully determine the customer’s needs, as well as to receive feedback on the extent to which those needs are being met [402]. Obtaining customer complaint information is to seek opportunities to improve product and service quality. Quality complaints have different problems that require different actions.

Based on customer complaint information, it is important to identify the “vital few” serious complaints that demand in-depth study in order to discover the

basic causes and to remedy those causes [177]. To improve customer focus efforts, customer complaints should therefore be treated with top priority. Records and analyses of customer complaint reports from the field furnish useful product-control information. Such information reflects the effectiveness of control programs and highlights those nonconformities upon which more aggressive corrective action must be initiated [114].

Obtaining customer satisfaction information is essential for pursuing customer focus efforts. Intensive examination of finished products from the viewpoint of the customer can be a useful predictor of customer satisfaction. Such information includes data on field failures and service-call rates, and analysis and reporting of customer attitude trends regarding product quality. Such information is valuable for new product development [114]. The results of customer satisfaction surveys can be used to take immediate action on customer complaints, identify problems requiring generic corrective action, and provide a quantitative measurement of customer satisfaction [177].

3.3.6 Strategic quality planning

The organization's policies, directives and guidelines provide the definitions for major corporate concepts and instructions regarding minimum requirements for issuing and communicating quality policies, directives, guidelines and planning. In other words, it describes principles, standards, and working attitude of the organization. Improving quality is a long-term competitive strategy [26] [87] [175] [285] that requires a long-term management orientation. All emphasized the need for a firm-wide strategic approach focused on better serving the needs of the customer [193].

The intent of a strategic planning is to communicate the organization's values, aims and ambitions, so that employees can make decisions that are consistent with and supportive of these objectives [241]. Creation of long-term vision of planning to align organization strategy in broader business context is a powerful motivating force that can be used to drive a process of change [162]. The policies statement is a powerful motivating force that can be used to drive a

process of change forward [394]. Wheelwright (1981) compared the role of operations management in the overall strategy formulation in Japanese and U.S. organizations [380]. He concluded that the top management must focus on long-term planning of operations' capabilities, including quality.

Organizations that can strategically plan and organize their resources are able to meet or exceed customers' expectations. The major components of Baldrige Award assessment are the thoroughness of strategy formulation (identifying the what and how of building competitive quality strength) and strategy deployment (translating the desired competitive quality strengths into activities such as human resource management, quality assurance in design and manufacturing) [5]. Quality policies are overall intentions and direction of an organization related to quality [402]. Quality policy and quality objectives are established to provide a focus to direct the organization. Both determine the desired results and assist the organization to apply its resources to achieve these results. The quality policy provides a framework for establishing and reviewing quality objectives [168] .

Translating identified customer needs into operational activities is a critical step in strategy deployment and requires an organization to establish effective infrastructure. In a study of quality-related decision making in six British companies, Dale and Duncalf (1985) observed that a more structured quality-oriented organization leads to more effective efforts toward increased quality [81]. Using approaches such as quality function deployment helps the organization translate customer needs into actions. Planning is also the first step in the famous Plan, Do Check Act (PDCA) cycle that has the dual purpose of preventing defects from occurring and continuous improvement. The strategic vision cannot be achieved if the management is not consistent enough in its communication. Many times management acknowledges what is required but does not communicate that adequately or frequently to employees [374]. Yukl define planning and organization as determining long-term objectives and strategies, allocating resources according to priorities, deterring how to use personnel and resources to accomplish a task efficiently, and determining how to improves coordination, productivity, and effectiveness of the organizational unit [398].

The principal management tool with the highest satisfaction rating is strategic planning [270]. Many organizations view the implementation of an ISO 9000 quality system as a strategic planning element in the medium-long term [20]. The strategic and operational plans must focus on continuous improvement and their performance must be validated using factual information, benchmarking and trends [67].

3.3.7 Processes Management

The management literature stresses the importance of identifying suitable process quality improvement opportunities because of their significant impact on cost reduction, quality improvement, and organizational positive re-enforcement of such efforts [331] [7]. However, all advocate that a strategic approach to better understand the customer requirements require an involvement of continuous process improvement and major quality initiatives [75]; [87] [177]. Deming (1986) remains a salient proponent of the process QM as a means of optimizing process performance [87]. The cost of non-conformance of quality increases with the magnitude of non-conformance [344]. Process improvement is aimed at this final objective, especially in manufacturing [143].

QM fosters process-oriented thinking, all processes must be improved and identification of process-based errors is essential. A process-oriented approach should also be applied in the introduction of the various process management strategies. Process quality management essentially involves identifying critical components of the manufacturing processes and improving them to ensure the superior quality of products at economical costs [6]. Deming (1986) advocated that improving product quality should not be dependent on mass inspection [87]. Inspection to ameliorate quality is very late, ineffective, and costly. Quality comes from process improvement and not from inspection.

The core idea behind process management in QM is that organizations are sets of interlinked processes, and that improvement of these processes is the foundation of performance improvement [87]. The QM philosophy focus is on continuous improvements and enhancements in business processes to cost-



effective and reliable incremental increases in productivity, quality, and profit margin [166]. Process control and continuous improvement emphasize the constant review of processes to identify better ways of delivering products and/or services. This constant review enforces a broad scope of activities on workers and, usually, a significant increase in the amount of decision making [131]. Process management means ongoing improvement to manufacturing, transactional, and/or service processes to satisfy customers' needs and expectations by using preventive maintenance, workplace organization, and use of line-stop capability [120] [44].

All organizational units must develop, and continually improve, performance goals and standards for all processes and value streams in the system [171]. Identifying problems before they occur, and a timely response to early signs of problems is crucial to maintain accuracy and consistency of the product as well as the process, which are necessary to achieve quality [306]. Continuous improvement occurs when an organization pursues incremental and innovative improvements of its processes, products, and services through problem solving [11]. Galvin (1993) embraces the essence of Deming's point that a "quality system" designs in the capability for continuous improvement [123].

QM works on the notion that the overall quality of products can be enhanced by improving the quality of the processes directly or indirectly related to their creation. In addition to manufacturing (a direct process), supporting functions (marketing, finance, Research & Development...) play central roles in attaining the operations more effectively. The quality improvement efforts of an organization must cover all phases of production (pre-production, production, and postproduction) and all functional areas (purchasing, manufacturing, and support functions) [5]. The Baldrige Award recognizes this linkage by identifying four major focus areas for managing process quality effectively: design of products and services, production and delivery processes, support business processes, and suppliers' quality performance.

Cardy and Dobbins (1996) point out that "Workers are trained in the use of statistical techniques and use these as tools to determine if a process is 'in control' [57]. In effect, the workers themselves have the means and responsibility for determining if the production or service process is stable . . ." (p. 6). Underlying

the principle of continuous improvement are the assumptions that: various functional systems of the organization are interdependent, so that improvement anywhere in the organization results in improved customer satisfaction, and improvement of these systems is always possible [57].

There are two challenges that construct a change in QM, introducing a change / improvement for the better and ongoing / continuity in a system. Lacking one of those elements would not be considered a successful change in QM. For instance, the expression of "QM as usual" contains the element of continuity without improvement. On the other hand, the expression of "breakthrough" contains the element of change or improvement without continuity. Our approach of quality change is twofold and contains both elements of "change" and "continuity". In this context, continuity refers to activities directed toward maintaining current technological, managerial, and operating standards and upholding such standards through training and discipline. Under its continuity function, top management performs its assigned tasks so that employees can follow quality procedures. Change for improvement, meanwhile, refers to activities directed toward elevating current standards by seeking ground for improvements. The twofold view of QM thus boils down to one precept: maintain and improve standards for QMI.

3.3.8 Summary of quality elements

The above section provides a base for five quality elements perceived from the literature survey presented above to conduct our study. The familiar points of the above literature survey include:

- Top management
- Strategic quality planning
- People (training and learning; participation and involvement)
- Process management

- Customer focus

It is urged in this thesis that the concept of communication-to-inform process (see section 2.3) ties up all dimensions of QMS together. All quality elements are connected by the force of information and communication. It acts as a common binding element. When top management interacts with employees, the flow of information and communication is helpful to make the employees clear about QMS and working dimensions including process management and strategic quality planning implementation. When employees interact with top management, the factor of contribution and trust on the system develops and provide the base line to develop and improve strategies. The successful implementation of QM is highly dependant on way of information and communication among all actors of QMS. *i.e.* top management, employees, supplier and customer. Top management role to spread all necessary information and communication with people plays the vital role to manage processes and to implement strategic planning to achieve customer satisfaction. Authentic communications are different from the simple transmission of information. Communicating with employees in a manner that encourages and invites them to think and act differently, rather than just saying what the organization think they should think, say and do – that is the difference [180]. Studies indicate that perception of open communication leads to contribute employee's feelings of satisfaction, their commitment to organization and their confidence towards the top management [374]. For quality managers, communication skills are crucial because quality involves different formal and informal communications at different level of the organization. Communication to inform portrays organizational QM as a phenomenon embedded in employees. This perspective suggests that communication to inform can be viewed with the help of training as a manifestation of QM values to be implemented.

Quality is not a quick fix to address management problems. It is not a program, but a transformation. As part of this effort, top management must recognize the need for assessment, strategic planning, and the development of a long-term, integrated organization-wide approach. Top management is needed to establish policies defining the positions the organization will take in regard to quality. Top management is also needed to cultivate a customer's orientation and

provide all employees with ongoing training and learning. These arguments notwithstanding, success or failure will rest upon the correct assessment of how to achieve customer-defined quality criteria and the kind of top management required to get the organization mobilized in the most cost-acceptable way.

3.4 Summary

This chapter started with defining quality and QM. Then QM elements are presented with the help of literature survey using various resources: approaches of quality experts (Deming, Juran, Crosby, Feigenbaum, Ishikawa, Taguchi, Shingo, Peters and Imai), measurement studies and quality awards. This chapter provides a theoretical rationale for the QM in organizations. Based on the above literature and the case studies presented in chapters six, seven and eight, QMI (quality management implementation) model will be presented in chapter nine.

4 ISO Standards for Organizations

4.1 Introduction

The purpose of this chapter is to explicate the role of ISO 9001 QM standards and its core values that aim to anticipate the QM activities within an organization. The examination of the literature described by the researchers on ISO 9000 can be useful in the context of quality activities in the industrial environment. This chapter presents a brief summary of ISO 9000 standards for concept and principles of QM. An examination of the ISO 9001 standard inspired the observation of QM implementation in the automobile industry (refer to case study 1 – chapter six) that had already engaged in a QMS and ISO 9001 certified. Section 3.1 presents an introduction to ISO 9000. Section 3.2 describes its origin and requirement. Section 3.3 offers a synthesis of the literature survey of ISO standards. The QM principles for ISO standards are described in Section 3.4. The section includes certification definition, certification reasons and its implementation approach. Section 3.5 discusses advantages and critics of ISO certification. Section 3.6 presents the core values of ISO 9000. Finally, Section 3.7 summaries this chapter.

4.2 ISO certification

Nowadays, organizations invariably have to cope with a constantly changing and challenging mode where an advanced level of continuous competitiveness is not sufficient without essential tools and measures for achievement. Quality is considered to be the baseline to achieve the required conditions for assuring an organization's survival and reaching a superior competitive position by using clear principles like established by the ISO 9000 [104] [377].

Although acquiring the ISO 9000 certification is voluntary, competitive pressures arising from global and local markets provide a strong reason to get certification. Deming (1986) argued that business contracts should not be awarded on the basis of price alone. A possible way to support this approach is to grant business based on quality [298]. To distinguish high quality suppliers, purchasers often send auditors to audit the production and quality processes of the suppliers. These second party audits have two shortcomings. First, there are too many buyers

auditing the same supplier and the result is over-auditing and a waste of resources. Second, when foreign suppliers are involved, geographic distances and cultural differences make audits difficult and very expensive [21]. However, rather than having every purchaser assess all its suppliers, a set of the standards had to be adopted by a supplier and easily audited by third-party (a certification institute, which itself has been accredited by a national accreditation body) certification to avoid multiple assessment of suppliers by various purchasers. The aim was to design an approach by which suppliers' QM systems could be audited and certified by an independent third-party authority which would provide objective evidence for all purchasers [322] [298] which indicates that the quality system meets the requirements of the ISO 9000 series [47].

4.2.1 Origins of ISO

The International Organization for Standardization (ISO) is based in Geneva, Switzerland, and was founded in 1947 for the purpose of advancing standardization around the world. Despite the common perception, the acronym ISO is not derived from the name of the organization. ISO is a word derived from the Greek “isos”, meaning equal [93]. The ISO 9000 series of quality standards were drawn up in 1987 by the ISO, and has since become the international quality standard [116] [370] and are continuously revised and updated. The original ISO 9000 series consisted of five standards: ISO 9000, 9001, 9002, 9003 and 9004, plus ISO 8402 (published in 1986 and it focused on terminology) [8]. The first two editions of the ISO 9000 series published in 1987 and revised in 1994 had a system that focused on enabling the enterprises to produce the same quality of products every time by specifying the policy, procedures and instructions in a quality handbook [172].

The revision of ISO 9000:2000 extended to three standards: ISO 9000:2000, ISO 9001:2000 and ISO 9004:2000 [8]. With the revision in 2000, the focus on customers and continuous improvements became stronger. The circles and arrows in ISO 9001:2000 symbolize a dynamic and continuous process (see Figure 4-1). It promotes the adoption of a process approach when developing, implementing, and improving a QMS [154]. The process approach is one of the eight QM principles

upon which the entire ISO 9000 series of standards is based. The process approach is a powerful way of organizing and managing how work activities create value [8].

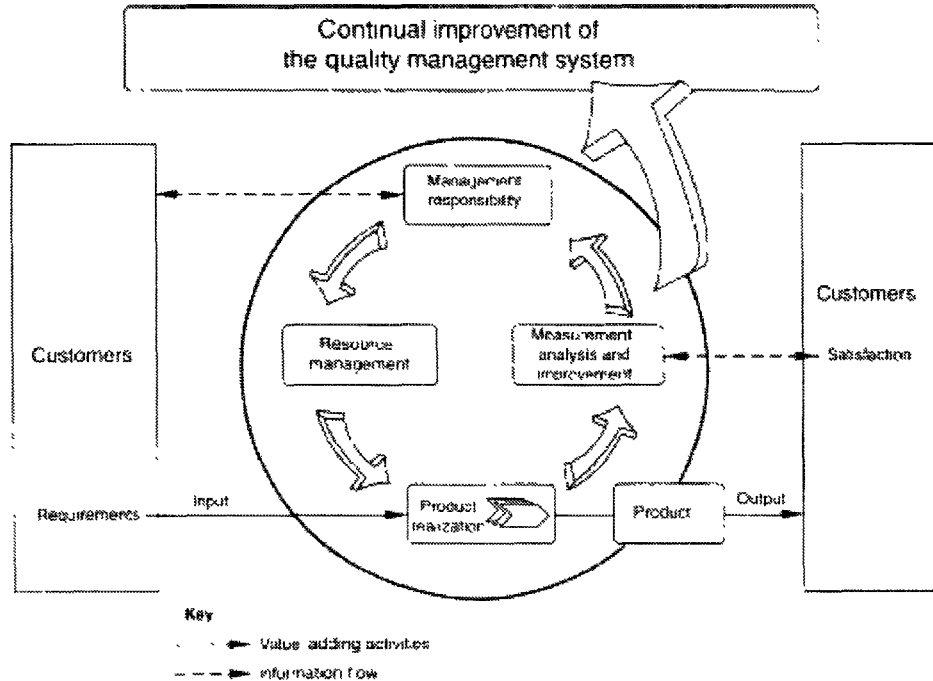


Figure 4-1: Model of a process-based quality management system (ISO 9001: 2000 (E))

4.2.2 What ISO requires

ISO 9000 is mainly concerned with the QMS, *i.e.*, whether a firm has done everything to ensure that its products conform to the customer's requirements [392]. The standards in the ISO 9000 series are considered to be generic standards for QM in the sense that these can be applied to any organization in any sector (independent to the size, kind of products manufactured or services provided, in private and public organizations, including government services). ISO 9000 requires a high level of documentation plus evidence that the intended quality is being delivered to the customer. This standard identifies the basic attributes of an organization's QMS and specifies requirements to be fulfilled in accordance with standards specified to demonstrate its ability to consistently design, produce, and deliver products and services with the same quality [8].

4.3 Literature review on ISO standards

Numerous articles about ISO 9000 exist in the literature written by researchers and practitioners. Major works are primarily prescriptive or descriptive and relate to such issues as implementation steps, justification for certification, benefits and costs of certification [156] [303]. The literature is full of discussions on the pro's and con's of the ISO 9000 series, however, most of them agree that ISO 9000 series provides a clear focus on certification and the use of quality systems in relation to the development of a QM culture, organizational change and business improvement [383].

One strand of literature on ISO is focused on the evaluation of the well-established international standard: the ISOs e.g., [53] [264]. Some, such as Ebrahimpour et al., (1997) [98], and Delmas (2002) [85], investigated the ISO 9000 certification experience of manufacturing firms in the US. Others focused on firms based in New Zealand e.g., [1] and Europe, e.g., [112] [289] and [341]. Although most authors reported an improvement in quality control, productivity and customer satisfaction, a number of scholars also pointed to the high transaction costs [98] [297] [341] [353]. These studies provide an understanding of the experience of developed countries in implementing ISOs.

For a number of years QM appeared to be the most popular quality strategy [224], however, it is now generally accepted that ISO 9000 has become the most prevalent global quality initiative [356] [405].

Numerous studies have presented evidence that ISO 9000 certification enhances other quality initiatives, particularly QM [25] [202]. Empirical studies have addressed issues such as costs and benefits of certification [21] motivation for adopting ISO 9000 standards [10] [25] significance of complying with ISO 9000 standards [25] [10], and the effects of registration on business performance and operations [224] [25]. Several comprehensive studies have been conducted on the implications of ISO 9000 registration on sourcing practices [387] and on competitiveness [10].

Several studies indicated that ISO 9000 certification results in the perception of higher quality [405], this outcome would seem to imply only that the

certification effort has served as a public signal that QM is being practiced [10]. However, these studies do not address the fact that quality is no longer defined as achieving a specified level of defects. Instead quality can be defined according to a number of dimensions of importance to the customer [130].

Wiele et al., (2000) provided a summary of several research projects on ISO 9000 [383]. He argued that obtaining an ISO 9000 series certificate of registration only requires a shallow change in an organization, for example: writing down what you are doing and acting accordingly. The reasons for implementing the requirements of an ISO 9000 series quality system are most often related to external demand [383]. The summary of research findings are presented below:

Witcher concluded that major motivation for Scottish organizations (survey of 1500 organizations) to seek certification was the demands of customer and requirement to ameliorate the organization in terms of performance [391]. Taylor concluded that certification was driven largely by external forces with the help of a survey commissioned in Northern Ireland (2000 organizations - public and private sectors hiring 10 or more people) [349]. Lloyds Register Quality Assurance argued that the certification outcomes ameliorate with time through a UK based survey by interviewing 400 managers to determine the causes of ISO certification and its effect on organizations' business [219]. Buttle indicated the reason as widespread willingness to recommend registration was associated with confidence, satisfaction and benefits experienced [54]. Vanguard Consulting Ltd [362] concluded that certification success is linked with its broader implementation rather some sort of obligation [362]. Brown and Wiele [48] found two major reasons for certification which were 'to maintain and/or increase market share' and 'to improve efficiency' from 500 ISO 9000 series certified organizations in Western Australia where 160 organizations responded to the survey. Important benefits included awareness of problems and quality. Drawbacks include increased paperwork, high costs involved with certification and presence of customer dealing with non certified organizations [51]. Wiele (2000) concluded from the above literature studies that the direct success measure for the implementation of an ISO 9000 standard is the certification process and award of the certificate [383].

A study conducted by Deloitte and Touche (1994) found that 80 % percent of the respondents believed ISO 9000 registration influenced their selection of suppliers [86]. The ISO 9000 standard requires that firms have in-house standardized and replicable routines and procedures for product design, manufacture, delivery, service and support, but whether implementation of such a standard is helpful to organizations is not known with certainty [16] [137].

Naveh and Marcus (2005) reported that among studies which support the benefit of implementing ISO 9000 including: [28] [395] [367] [93] [328]. Elmuti and Kathawala (1997) supported the statement that productivity, product's quality in addition to quality of work life improved due to certification [103]. Brown and Loughton (1998) concluded advantages of improved quality awareness, high awareness of problems and increased product quality, but did not observe improvements in terms of productivity and costs, wastage charges and staff motivation [49]. On the other hand, some literature presented that the above advantages are not at all produced in various studies. Study demonstrated that ISO 9000 did not necessarily guarantee product quality [159].

Elmuti and Kathawala's (1997) demonstrated the ISO 9000 certification had better and improved quality of work life compared to the non-certified one (comparison of two manufacturing plants in a large U.S. organization) [103]. Advantages include increased employee productivity, morale, and goal congruence while it decreased absenteeism, rework, and defects. Coherent effects were observed in Northern Ireland [235], Norway [342], North America [323] and UK [68].

On the contrary, Sharma [323] mentioned results which lack advantages of ISO that have been reported by [30] [157] [296] [395]. Beattie and Sohal (1999) survey study included 50 Australian organizations, where one fourth could not describe any related strategic benefits and only 4% stated improving their profitability due to certification [30]. Hua et al.'s (2000) survey study was composed of 100 organizations in Shanghai, where no significant differences in quality related performance measures was found between organizations with ISO 9000 certification and those without [157]. Yamada's (2001) survey study included certified Japanese organizations demonstrated same results where

organizations could not identify the effects of ISO 9000 certification on estimated expenses and profits of large companies listed on the Tokyo Stock Exchange [395] [382]. Several studies described ISO certification as not the probable cause of performance specification to QM by itself [290], [352]. Highlands (1995) questioned whether ISO 9000 was worthwhile based on the relationship between cost, time, effort, paper work and customer needs [149]. Larson (1997) questioned top management's commitment and wondered if certification was necessary [201].

While considering the literature analysis, it seems that some managers have not understood the actual role of ISO 9000 certification. A possible explanation is not distinguishing between conformance and performance specification by those managers [352]. ISO certification states that an organization's system is potentially capable of producing quality products and services, thus conforming to specification. However, performance specification is dependent on its utilization in daily routine activities to standardize the process activities [352]. Askey and Dale (1994) mentioned in their study that they found managers moving towards their old classical practices after obtaining certification. Managers chose to move back to their traditional way and their commitment towards QMS and improvement plans was short lived [9] [48] [43].

Powell (1995) concluded that the soft factors such as (employee empowerment, top management commitment) had a big impact on QM performance rather than the tools and techniques such as ISO 9000 certification and benchmarking [291]. The literature review indicates that certification is a potential path to QM [9] [35] [48] [43]. That said, in ways to implement the QM, there are different views.

4.4 QM principles for ISO certification

The ISO standards specify requirements and recommendations for the design and assessment of a management system. It sets out a framework for the systems that an organization should have in place to control its internal processes. According to the ISO 9000 approach, any organization may establish a quality system by implementing a ready set of eight specific aspects of what constitutes quality. The objective of these guidelines is to control variation in the required

specification of a product/service. Description of eight guidelines of ISO 9000 is mentioned below [168]:

- Customer focus: Organizations need to understand current and future customer needs, and should meet customer requirements and strive to exceed customer expectations.
- Top management commitment and support: Leaders must establish and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.
- Involvement of people: People at all levels are the core of an organization and their appropriate involvement enables their abilities to be used for the organization's strategy. Training and learning of personnel to understand the operational aspects of the QMS and support is necessary.
- Process approach: A desired result can be acquired more expeditiously when actions, activities and related resources are managed together as a process that involves planning and control, inspection and performance review.
- System approach to management: Identifying, understanding and managing interrelated processes as a system contributes to the organization's strength and effectiveness in acquiring its objectives.
- Continuous improvement: Continuous improvement of the organization's overall performance should be a lasting aim of the organization.
- Logical approach to decision making: Effective decisions are based on the analysis of data, facts and information.
- Mutually beneficial supplier relationships: An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

These eight QM principles form the basis for the QMS standards within the ISO 9000 family [168]. An approach including these principles is also applicable

to maintaining and improving an existing QMS. An organization, by adopting the above approach creates confidence in the capability of its processes and the quality of its products, and provides a basis for continual improvement. This can lead to increased satisfaction of customers and other interested parties and to the success of the organization.

Each of these aspects must be described through a written documentation explaining how each process is managed, and an independent auditing agency has certified that each activity is performed as described by the standards. The outcome is the formalized documented system of QMS that identifies how the organization works within the framework of the ISO 9000 standard [116]. The documentation is continuously reviewed and modified to match the changing requirements such as design changes or process improvement. Internal and external audits are performed on regular basis to ensure that a coherency between day to day practice and the formalized documented QMS (policies, procedures, and work instructions). These audits are to ensure that all processes which have a direct effect on quality are carried out under controlled conditions. This is to determine that the correct sequence and specification of products is built. An organization will fail the audit if any of these aspects is not present and functional [78].

During the last several years, there has been a major increase by the manufacturing firms in the world to seek certification to the International Quality Standards ISO 9000. These have been rapidly accepted as a standard for documenting processes and procedures [389].

4.4.1 What certification means

The ISO 9000 series was the fastest growing standards in history and was very popular from the start [32]. ISO 9000 is about quality systems and about consistency. It aims to give customers confidence in their suppliers by assuring them that the suppliers have in place QM processes that deliver consistency. ISO encourages but does not of itself in anyway certify, assure or monitor product quality. Moreover, ISO 9000 standards themselves are not expected to define or

dictate the contents of organization specific quality systems. Neither is ISO 9000 a product nor service quality label.

Certification means audited compliance to a generic applied standard of the ISO series. The ISO series was produced to allow a structure which can assure that the QM principles are distinguished and applied [116]. ISO certification, by itself does not guarantee that the quality of products or services of an organization is better than the other organizations [324] [47].

ISO 9001 certification demonstrates that an organization has implemented the minimum level of quality control. Beyond this symbolic role, which actually can lead to significant business benefits in the form of simplified and standardized business relationships, ISO 9001 standards are used to improve the internal effectiveness of the production processes [180]. Quality certification requirements for ISO 9001 contain certain specific requirements mentioned in eight guidelines presented in the above section.

If an organization meets the ISO 9000 standards following an external audit, the organization is issued an ISO 9000 certificate that includes the scope of certification and the effective date. While certificates are typically issued for 3-year periods, compliance review is performed every 6 months to ensure that it is still fit to carry the standard.

4.4.2 Reasons for seeking ISO certification

From the early nineties, many scholars worked on exploring the adoption of ISO 9000. Some suggest that the diffusion is based on institutional pressures [141]. Other scholars suggest that firms might adopt ISO 9000 as they view certification as a regulatory or export requirement [16] [359]. The European Community requires firms that sell safety sensitive products in the European Community to conform to ISO 9000 standards (or alternatively submit regular samples for testing). Therefore, the voluntary standard is linked with regulatory pressure [72].

For buyers of safety sensitive products such as brake components, for example, low defect rates are crucial [243]. However, buyers often have difficulties identifying (ex ante) suppliers that provide consistent product quality because the suppliers' underlying quality attributes are difficult for buyers to observe. This is because such attributes often are complex, embedded, and difficult to measure. As a result, some buyers have demanded that their upstream supply partners adopt ISO 9000 to reveal their otherwise difficulty to observe attributes [351]. Large industrial purchasers such as *Eastman Kodak*, *British Telecom*, *Caterpillar*, *DuPont*, and *General Electric* urge suppliers to adopt ISO 9000 standards [145] [359].

Various studies reported that customer requirement is one of the major reasons for seeking ISO 9000 certification in US organizations [22] [98] [405] [387]. The same case was also demonstrated for Belgian [365], Greek [356], New Zealand [212], Swedish [58], and Australian [30] organizations.

Creating more efficient processes has been identified in other studies as a source of motivation for ISO 9000 certification [98] [365] [58] [387].

Competitive pressure is also considered as a viable motivation by a large number of organizations seeking ISO 9000 certification [387]. Similar results were observed in other studies that mentioned competition and market pressure for pursuing ISO certification [98] [58]; [30] [212].

Some 64 % of the reasons provided by European organization were the expected potential advantages in internal processes and procedures. This further demonstrates that these organizations seems to be more motivated and aware of possible benefits offered by ISO 9000 certification than US organizations [387] where external market forces remain the key drive to seek certification [22] [98]. Carlsson and Carlsson (1996) explained this difference in the approach due to the difference in commitment towards quality and understanding of the potential that certification offers for improvements [58].

Wither (1997), reported that ISO 9000 certified organizations experienced improvements in internal communications significantly by quality system-in-use [390]. European organizations identified improving communication as a primary

reason for getting ISO certification [389]. European organizations in the above study perceived improving communication as a viable motivation for seeking ISO certification. The benefit of improving communication was among the top five reasons for ISO certification [389]. Another study conducted for ISO 9000 certified organizations in USA demonstrated that poor communication was recognized as a barrier to implementation of ISO 9000 [98]. It is urged that employees are at the centre of QM because they define, plan, organize and manage QM activities in organizations. To meet the quality goals and objectives, people by using communication to inform all actors of QM in organizations. Communication is a vital component to implement a quality standard. The focus is on employees and how they can be organized to implement the organizational quality standard (*i.e.* ISO 9001). To make employees involved in QM and organized for implementation, communication to inform and ongoing training are pivotal. A quality department performance is dependant upon the performance of the quality standards, in other words, on implementation of QM. Quality departments and teams have substantial responsibility but dependant upon the cooperation of all other departments who use those quality standards.

4.4.3 Implementing an ISO 9000 approach

A quality system implies an organization's responsibility for its structure, procedures, processes and resources for implementing QM in a way that it complies with the organization's quality policy and objectives. An ISO 9000 quality system comprises the description and documentation of all business activities through people and processes as it is the people that make the system run. One can show the whole process by flow charts, which provide a clear image of the processes that deliver the service, the people involved and the relevant interactions among them. Each process is divided into many layers of sub-processes, activities and tasks that need to be defined. The main reasoning in defining organizations in these terms is that it is possible to represent the view of the consumer, who becomes the focus of each process. Meeting the requirements of the customer, rather than those of the managers, becomes the key objective [40].

The ISO implementation involves several main aspects to address including top management, process management, training and learning of personnel, standardized procedures, clear communication with customers and suppliers, and evaluation and selection of a third-part certification agency [94], corrective and preventive actions for continuous improvement [322]. The implementation of standards requires that the workforce adapt their working styles to the four principles underlying ISOs [118]:

Say what you do: document each step in the organization's business process.

Do what you say: ensure that all processes adhere to the written procedures.

Show what you have done: document evidence that the QMS and/or EMS meet ISO requirements and that the quality and environmental standards are being implemented effectively.

Verify: conduct periodic internal audits to ensure the continued suitability, compliance and effectiveness of the QMS and/or EMS.

The time needed to obtain ISO 9000 certification generally varies from one to two years [322]. However, the time can vary according to several factors including how well developed the management system was before ISO, resources available and management commitment [259].

The overwhelming majority of firms experience two major areas of difficulty in implementing ISOs during the transitional period – documentation and **resistance to change** – and this in turn affect their competitiveness [340]. As explained in chapter three, the challenge to introduce a change is twofold in QM. There is a need to bringing a change and ongoing / continuity in the QM system. Lacking one of both would not be considered a successful change in QM for implementation. The process of change initiation is explained in *Figure 4-2*.

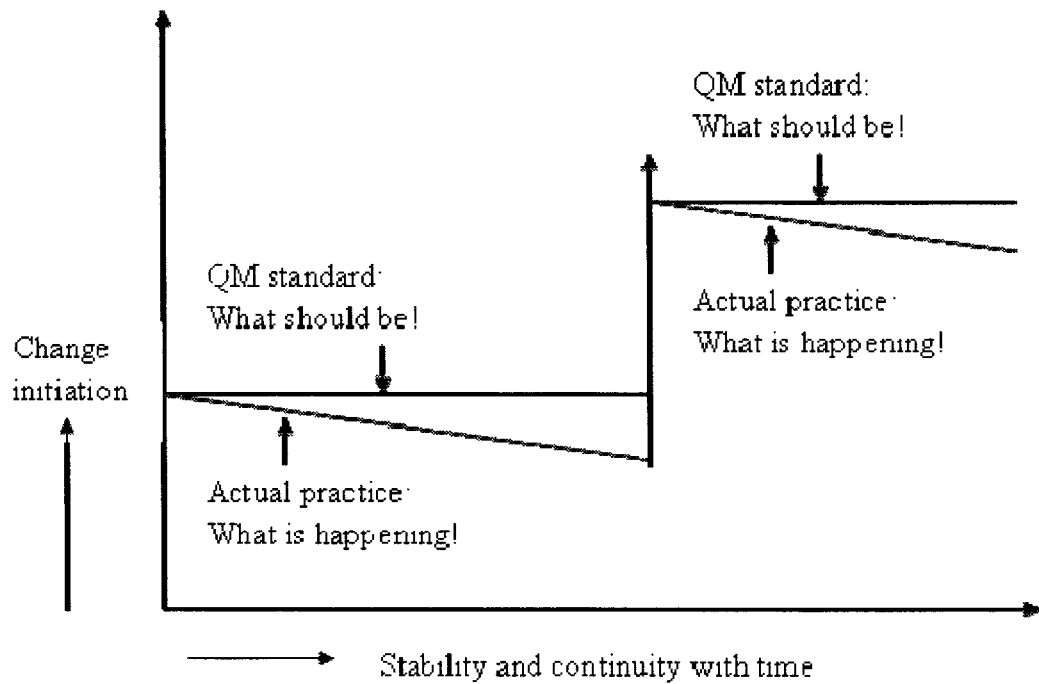


Figure 4-2: Process of change initiation and stability of QM through quality awareness

Our approach of quality change initiative is twofold and contains both elements of “change initiation” and “stability and continuity”. In this context, stability and continuity refers to activities directed toward maintaining QM standards and policies with the help of continuous training and communication. Top management interacts with employees to implement QM standards. Change initiation refers to activities directed towards improvement of existing situation by seeking possibilities for improvements.

4.5 Advantages and Critics of ISO 9000

According to Naveh et al., (1999), certification is similar to having a college diploma [263]. The motivation of many firms for certification can be explained with the help of the opinion of the general manager of an organization that ISO is a brand name per se [392]. This approach is well explained by Spence (1973), who argued, that to differentiate high productivity job applicants from low productivity ones, independently of whether students learn anything in the process of attending college [332]. As achieving a diploma involves effort which is assumed to be more difficult for less productive students, high productivity students are more likely to complete a college degree. Accordingly, completion of

the management steps needed to certify with ISO 9000 can differentiate facilities with desirable organizational attributes [351]. Moreover, Cole (1998) suggests that firms may make ISO 9000 “their primary instrument for signaling quality to their customers” [72].

4.5.1 Advantages

Benefits of ISO include consistency in procedures and practices through a declared commitment to good business practices and continuous improvements and a better image, [93] defined roles for each team member, elimination of loose practices and eradication of wasted work [154]. Implementing the standards of ISO 9000 will most likely improve the extent of documentation of products and processes within the firm [298].

ISO certification is not a risk free undertaking [387]. Moreover, a high first-time failure rate pervades the experiences of US firms [126]. These risks of ISO 9000 implementation are drawing increasing attention to the benefits of achieving certification. The higher number of certified firms in Europe than the US (historically three to five times greater) [10] suggests that European firms may have a better handle on the certification process or a better understanding of the impacts of ISO 9000 on organization operations and outputs. While ISO 9000 may continue to serve as a market qualifier in some markets (*i.e.* the European market) [21] [98] [390] its value may be judged by many firms on the basis of its contribution to actual product or service quality. The willingness to pursue ISO 9000 registration could depend heavily upon evidence that registration will contribute to improve quality for those factors perceived by the firm as important to competitive success [387]. The ISO certification, which is based on periodic reviews, implies the obligation to maintain the QMS in order to ease its adaptation to new conditions and requirements [104].

Based on a sample of certified firms in Spain, Santos and Escanciano (2002) argued that the most significant benefit of ISO 9000 certification is a better understanding of an organization’s processes and responsibilities [314]. Schuurman (1997) classified advantages into the tangible (increased efficiency and

improved quality of the operations), intangible (increased competitiveness in new and existing markets, improved employee motivation, improved working conditions due to the establishment of working procedures, the quality system and the initiation of systematic continuous improvement after certification and post-certification benefits (inventory control, decrease of quality costs, reorganization, re-engineering and internal optimization of processes) [322]. Batchelor (1992) found that the advantages of implementation were procedural efficiency and error rate reduction and not market share, staff motivation, or cost reduction.

Several studies conducted by various researchers [221] [81] outlined a cluster of significant benefits from ISO 9000-based QMSs such as: improved quality system; improved customer satisfaction; continuous improvements; standard processes, structured documentation procedures and better control; reduced costs; reduced wastages; reduced rework; less conflicts, claims and disputes; and enhanced consistency and better image [169]. ISO certification could be useful to consumers as a sign of the good quality of the products offered by the companies [168]. All small and medium firms wishing to go beyond the ISO-9000 requirements towards QM must ensure a wide implementation of quality constructs [73]. ISO certification plays complementary roles to achieve internal benefits [59] and external benefits are associated with increased demand for a registered site's product or service respectively [252]

Atwater and Discenza (1993) classified their sample of 29 firms based on size and gathered information on ISO 9000 registration costs and benefits [22]. They report that their respondents listed the following as ISO 9000 registration benefits: improvement in (1) plant operating efficiency, (2) customer satisfaction, and (3) competitive position. There were reductions in training time for new employees, and in scrap and rework. They found that large (annual sales exceeding \$100 million) and medium (annual sales between \$25 and \$100 million) firms were aggressively pursuing ISO 9000 registration. Only 38 % of the small firms (annual sales less than \$25 million) in their sample led to ISO 9000 registration. Two thirds of the respondents felt that the benefits of registration exceeded costs. According to Geraedts et al. (2001), ISO creates conditions for various advantages including: transparent processes within the organization, enabling controlled

changes to be made; periodic internal and external audits to maintain the system through rigorous document control procedure.

4.5.2 Critics

Among others, ISO is sometimes criticized as it is not connected directly enough to product quality [336]. *i.e.* an organization can still have substandard processes and products despite getting its ISO certificate. Because ISO registration only ensures a quality system exists and cannot guarantee its operations (how to develop and design more effective and authentic products). Moreover, ISO does not bound organizations to provide information if the clients are satisfied with their products. ISO standards focus on documentation, thus, giving impression to some managers that ISO is paper-driven approach and that it keeps track of non-compliance only [77]. For this reason, ISO 9000 should not be viewed as an alternative of any complete quality management system. ISO 9000 only ensures that a quality system exists, and cannot guarantee its functionality [79]. Because of the need to describe procedures and to keep track of non-compliances, ISO is often seen as a bureaucratic process involving manuals and record keeping [47]. Moreover, ISO does not provide guidelines about the appropriateness of quality investments (*i.e.*, level of investment, their timing, degree of activity, etc.) based on organization's requirements and strategic position [77].

Quazi and Padibjo (1998) pointed to the unexpectedly high costs of implementation, and the large amount of documentation required by the ISOs [297]. Ofori et al., (2002) revealed that there has been no cost savings in the Singaporean construction industry from implementing ISO 9000 [272]. In their studies of Slovenian companies, Pivka and Ursic (2002) also pointed out the high cost of implementing ISOs during the transitional period [289]. Extensive literature exists to challenge the criticisms commonly associated with ISO 9000 [77]. The literature is clearly divided in its assessment of ISO 9000, which is viewed as either a variant of QM or a paper-driven process of limited value. An examination of this international quality standard inspired the observation of QM implementation in the automobile industry (case study 1 – chapter six) that had already engaged in a QMS.

Some researchers argue that certification with a management standard may represent an attempt to communicate about desirable organizational attributes to parties that cannot observe them directly [351]. This aspect of certified management standards is inherent in their design and may be critical to their function, yet it remains little explored [16].

The ISO 9000 international standards emphasize the establishment of a well-documented, standardized quality system which may require significant costs either internal (employee training, monitoring equipment, improving technology usage, improving supplier relationships, etc) or external costs (consultant advice, training, calibration services and certification costs, etc). Moreover, costs may vary widely. These costs will be less for organizations which already have a quality system in place. This indicates that the requirements of the ISO 9000 series could be satisfied if they were a part of the organization wide QM program. ISO 9000 or any other QM program should not a "stand alone" program *i.e.* without implementation of the applicable standard. For this reason, we urge that it is vital to implement a QM standard. For this purpose, we describe a QM implementation model in chapter 9 after presenting case studies in chapter six, seven and eight.

4.6 Core values of ISO 9000

After reviewing the literature on QM, it was found that QM philosophy includes various concepts: top management, training and learning, customer orientation, strategic planning and policies, process management, employee involvement and participation, supplier quality management, measurement, quality system improvement, product design, quality information.

Many studies have been published which, in the opinion of the certified companies, view the certification as the first step on the stairway to total quality management (TQM) [350] [49] [214] among others). According to Zhang (2001) TQM is a management philosophy for continuously improving overall business performance based on leadership, supplier quality management, vision and plan statement, evaluation, process control and improvement, product design, quality system improvement, employee participation, recognition and reward, education and training, and customer focus [402]. However, the fact remains that for a large number of organizations that are engaged in QM, once the certification has been

obtained, they simply guide their resources to maintain it [106]. Many buyers rely on ISO certification to identify potential suppliers and in this case ISO certification plays an important role [116] [229].

According to several researchers, the ultimate objective of ISO 9000 is to raise the awareness and performance of quality throughout the value chain, and not only in operations [406]. We present our quality awareness model in chapter nine. Some studies have provided an empirical base to the affirmations of the existence of a relationship between a firm's technological status and the certification [49] Lee, 1998; [106]. ISO 9000 could be viewed as a documented system to manage internal business processes from the beginning to the end of a value chain. Obtaining and maintaining ISO 9000 certification is a continuous and costly process [323]. ISO 9000 certification cost can be very high (ranging from \$10,000 to \$300,000 per organization [22] [16]. With improved internal communications, feedback and training, the ISO 9000 standard seeks to help to enhance an organization's confidence in its ability to consistently maintain its QMS.

4.7 Summary

This chapter first presented an introduction and the origin of ISO. Then a literature review was described. Afterwards, importance of certification, reasons and implementation approach was presented. In addition, advantages and critics on ISO were studied. Then, the core values of ISO 9000 standard was presented to develop the ground for the development of quality elements which are presented in the case studies chapter (six, seven and eight) to propose a model formulated in chapter nine. These core values include top management, employee training and learning, customer orientation, strategic planning, process management, employee involvement and participation, supplier quality management, quality system improvement, quality information. The above values are also supported by the literature survey presented in chapters two and three. Chapter two, three, and four have provided a theoretical foundation for the research objective of this study. This chapter is helpful to observe and understand the ISO 9001 certification of first case study (refer to chapter six). Next chapter presents the QM standards for the computerized system in the pharmaceutical industry to provide base for second case study (chapter seven).

5 Computerized System Validation for Organizations

5.1 Introduction

This chapter presents a brief summary of Computerized System Validation (CSV) that defines the major concept and principles of a QM computerized system in the pharmaceutical industry. It is presented here in order to highlight how it is linked to the conceptual framework of this thesis beyond its purely technical attributes. In this light, the CSV demonstrates, in part, the relevance of the conceptual framework to QMI based on a quality-drive approach. Section 5.2 presents the introduction to validation. Section 5.3 describes the definition of a computerized system. The validation approach is defined in the guidance of regulatory health authorities of the European Union, France and the USA in Section 5.4. Section 5.5 discusses the validation process. The section includes a quick guide of major phases of validation. Section 5.6 presents the roles and responsibilities associated with CSV in an organization. Key validation deliverables are also presented in this section. Section 5.7 describes the process of change management (CM) which is a critical part of CSV. The section includes a framework with major types of changes, the CM process life cycle and discussion. The discussion and conclusion is presented in Section 5.8. Finally, Section 5.9 summarizes the chapter.

Various parts of this section were drawn from my previous publication of a book chapter in the *Handbook of Research on Informatics in Healthcare and biomedicine*, published by IDEA Group Publisher, USA in 2006 and the upcoming publication of book chapter in the *Handbook of Research on Distributed Medical Informatics and E-Health*, published by IGI Global Publisher, USA in 2008. Both book chapters concern a CSV quality approach for pharmaceutical industry.

5.2 Introduction to validation

The term validation appeared in the sixties, and has become a topic of business concern today and is considered to be one of the core issues in the pharmaceutical industries in terms of satisfying regulatory requirements. In the recent past, increase in the use of CSV compels quality and validation standards to be more precise to meet industrial needs. The utility of CSV has been an important catalyst in the audits. Today, the pharmaceutical industry makes use of CSV for

several purposes (services, computers, equipments, process verification, change management, etc....) exploring the ways and means of how validation ensures the system in use is compliant and to decrease failure rates, risks, and long term costs, etc. Validation is vital and in fact, if the pharmaceutical organizations are not careful, they may run into several roadblocks that could derail the implementation and ultimately cost them more money concerning the validation of a computerized system. Currently, official inspections concentrate more and more on validation of computerized systems due to Good Manufacturing Practices (GMP) [152].

In recent years the introduction of computer systems for data handling in the pharmaceutical industry has increased [123]. Over the last three decades, the pharmaceutical industry has increasingly used computerized system to support the product development, less time in the registration of patents, product development, manufacturing, and production, etc. The failure to validate a computerized system can have significant financial and business implications from regulatory authorities including cancellation, delay in the issue of a license, product recalls, delay in submission to regulatory authorities, negative publicity, removal of distribution of a product or recall of a products, shutdown of the manufacturing plant, etc [233] [387].

World wide regulatory authorities (Food and Drug Administration - FDA, EC - European Council, AFSSAPS - French Agency of Health Safety of Health Products, Health Canada, and others) have issued rules, regulations and guidelines, which are aimed to ensure viable practices in the pharmaceutical organizations concerning public health. All these requirements to maintain the quality processes are ways to ensure that final consumers receive only safe and effective medical products. These authorities verify the required compliance before approving the license of the manufacturer. These requirements are available in several forms like GxPs: Good (Clinical, Laboratory, Manufacturing, etc) practices or BPF (Bonnes Pratiques de Fabrication), etc. Each country has its own interpretation of quality and compliance requirements for the development of systems and procedures to achieve quality, however, basic rules and principles remain the same and are universally applicable. These regulatory requirements are established to define uniform standards that emphasize the public health safety as a primary concern. In all cases, these regulations give an overview of minimum requirements and dictate

what must be done and by whom without specifying how it is to be done. It is the responsibility of management with their respective validation teams to identify schedules, priorities, and resources required for the preparation to meet these standards. Hence, the need for an appropriate form of QM is essential.

In this section a comprehensive treatment of CSV is addressed and roles and responsibilities involved are explained that can improve validation. For the validation specialist, the objective is to improve the utility and conformance of the system in the validation process. Such validation must always be designed from the point of view of the manager, user and compliance requirements. This section investigates the role of validation activities to accelerate the development of business-specific validation. Moreover, validation is compulsory for an information system to remain compliant with QMS in the pharmaceutical industry.

5.3 Computerized System

Several definitions are available to define a computerized system. We start with the principle described by European Parliament in the Annex-11 (Computerized System) relating to the respect of medicinal products for human use and investigational medicinal products for human use as “The introduction of computerized systems into systems of manufacturing, including storage, distribution and quality control does not alter the need to observe the relevant principles given elsewhere in the Guide. Where a computerised system replaces a manual operation, there should be no resultant decrease in product quality or quality assurance. Consideration should be given to the risk of losing aspects of the previous system which could result from reducing the involvement of operators” [101].

The American Food and Drug Administration (FDA) defines Computerized system as “Computerized System means, for the purpose of this guidance, computer hardware, software, and associated documents (e.g., user manual) that create, modify, maintain, archive, retrieve, or transmit in digital form information related to the conduct of a clinical trial” [113].

Validation is a process that requires close attention and we summarize a clear approach to validation that can be incorporated to quality in implementing

validation principles. We start with some general definitions of validation used by AFSSAPS, EC, FDA, and ISO. We go on to discuss a validation plan method that may be suitable in general in high assurance disciplines and then we link validation to quality. We conclude with some possible future research opportunities in computerized system validation.

The elements of a computerized system are shown in *Figure 5-1*.

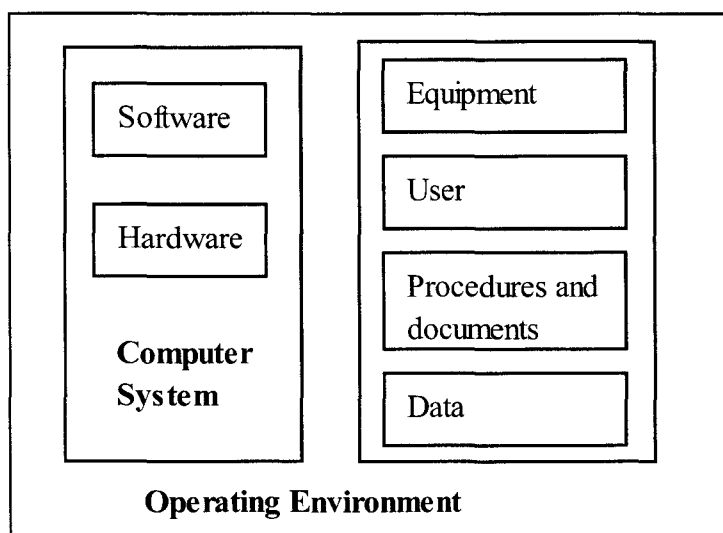


Figure 5-1: Elements of a computerized system

A computerized system may include operating environment (Unix, DOS, NT, etc) programming language (Basic, C++, Java, etc), data base (Oracle, Access, DB2, etc), any software, hard disk, processor, network materiel, data input, electronic processing and the output of the information to be used either for reporting or automatic control. It may include automated manufacturing equipment, process control systems, automated laboratory equipment, laboratory data capture system, clinical or manufacturing database systems, etc [160].

In this section, I used the regulations applicable via the European Union parliament for France and for America I considered the FDA as a reference authority. The aim of this methodology was to put together all the steps of validation that can help pharmaceutical organizations validate their computerized system through controlled specialization. All the steps and documentation required to better focus on validation and how to avoid barriers to achieving successful

validation are described in this methodology. This way, I provide a road map to deploy efficiently a validation methodology.

5.4 Validation Approach

Validation has remained one of the important issues in the pharmaceutical industry for many years. Validation is important in the age of international competition and rapidly changing technological environment not because of the regulatory requirements only but also for an effective viable approach in the long run for the computer systems used in the industry. Validation is vital to allow an organizational international competitive stance, growth and compliance requirements. The basic aim is always to ensure that the quality of the process is always able to develop a product that satisfies pre-defined conditions that respect all the applicable norms. Validation teams focus on their role in the development of quality orientation validation plans by providing valuable insight and guidance in order to keep pace with the latest changing technology. The major objective behind a validation strategy is always to ensure quality for all the deliverables of a computer system and to verify the compatibility with all compliance (functional, security, integrity, etc....) requirements. The Validation is defined by AFSSAPS as “Establishment of proof that the implementation or the use of every process, procedure, material, raw material or product, activities or system really make it possible to reach the anticipated results and the fixed specifications” (free translation from the French) [247].

The directives of 2003/94/EC define Validation as “The extent of validation necessary will depend on a number of factors including the use to which the system is to be put, whether the validation is to be prospective or retrospective and whether or not novel elements are incorporated. Validation should be considered as part of the complete life cycle of a computer system. This cycle includes the stages of planning, specification, programming, testing, commissioning, documentation, operation, monitoring and modifying” [101].

The FDA defines validation as “Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes”

[104]. It seeks to develop a proper validation plan and performance, document validation tasks, and assess software development.

Validation should be considered as a part of the complete life cycle of a computerized system [339]. Validation basically concerns all the steps in the production process, which could affect the final quality of the product [152]. Thus, it is important to specify the compatibility and usefulness of the computer system, and to define specifications and quality dimensions of computerized system under consideration before developing or purchasing. Therefore, the user requirements and system specifications documentation are equally essential [105]. The FDA in its guide indicated an expectation of a risk-based approach to determining which systems should undergo validation. Most pharmaceutical and biotechnology professionals have experienced the qualitative difference between taking high risk and low risk decisions. In low risk situations, one is often willing to gamble and reach hasty, if not faulty, conclusions. In high risk situations, one usually takes more time to gather and analyze all relevant information [408].

As defined in the ISO/IEC 17025 international standard, validation is the "confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled." So for validation, both the procedure and system components (hardware, software, etc...) that can affect the results of measurements needed to be validated.

As the validation of computerized system is a regulatory requirement for the FDA because of 21 CFR Part 11, so, validation can be treated as a proof of its suitability that is linked with the whole system's lifecycle to ensure that the system meets user requirements, ensures compliance expectations and will be properly maintained to guarantee a secure environment with accurate, reliable, and traceable information throughout its lifecycle. Validation is a process that begins with defining the requirements and ends with ensuring that the needs are consistently being fulfilled [59]. In short, validation is to assure that all associated risks of a computerized system are well managed.

Numerous life cycle models (waterfall method, enhanced waterfall method, Spiral model, V-model, CMMs, etc....) have been introduced in order to

accomplish software validation. In general, software validation involves a series of activities and tasks that must be planned and executed at required stages depending on the life cycle model used, software used, risk associated, and the scope of changes made as the project advances. This is based on several assumptions that an organized approach in using one or many or a combination of these models can result in fewer defects, thus, ultimately provides better results [360]. The documented collection of policies, processes and procedures is equally important.

5.5 Validation approach of a computerized system

The principles of good practices for the use of computerized system via validation are now well established as means by which quality is built into development of these systems. The purpose of this proposed methodology was to obtain and maintain the validation of computerized system by:

- assuring high degree of quality for all deliverables of any GxP computer system;
- ensuring that an organization's computer system and its use are in compliance with applicable regulatory requirements and internal policies;
- ensuring that the system is in compliance with all functional, reliability, integrity and security requirements;
- ensuring that the operation and maintenance of the system are under control.

Major phases of the validation of a computerized system producing documented evidence are described below:

- Network and infrastructure
- Validation master plan
- User requirements specification (URS)
- Risk analysis
- Supplier audit and vendor selection

- Legal requirements
- Functional specification
- Validation strategy planning
- Design specification
- Code review
- Implementation phase
- Testing phase
 - User acceptance testing (UAT)
- Qualification Phase
 - Installation qualification (IQ)
 - Operational qualification (OQ)
 - Performance qualification (PQ)
- Standard operating Procedures (SOPs)
- Trainings
- Verification and release phase
- Final validation report
- Maintenance and regular review
- Change management (CM)
- Decommissioning

Network and infrastructure tools: Infrastructure and network services including local area network (LAN) and wide area network (WAN), Intranet, security access, etc...must provide reliable, trustworthy information, data and

delivery and must be assured and maintained by detailed specification documentation (approved procedures) and change management.

Validation master plan: The master plan provides a complete documentation list for computerized system to be validated according to the business and process priorities and importance.

User requirements specification – URS: The URS is a definition of system requirements in terms of how the user perceives the system to operate in the intended use and environment. The URS should answer what user want to do or what the system is required to do for its users. It may identify integration with other existing systems, access the functional need (e.g., data presentation, records, reports...), regulatory requirements, working environment constraints, system performance, maintenance required, documentation required, etc... The final user should be involved in this phase to ensure a good understanding of the system requirements and the functionalities required of the installed system. All URS should be verified before final confirmation.

Risk analysis: One of the most important steps in the validation is defining the risk areas. In order to guarantee as high security as possible during routine utilization of the system critical functions have to be defined and a number of test runs have to be done [104]. Risk analysis includes strategy and methodology, risk associated with different parts, and action plans to minimize these risks. It should answer the solution against all identified risks. What has been agreed upon during the supplier/vendor process and specified during the continuous contact with the supplier might give additional advice to define critical functions and modules [111]. For validation of the software the risk analysis is effected at the module level [18].

Supplier audit and vendor selection: Pharmaceutical companies are held responsible for any inadequacy observed by the regulatory teams in their selected supplier. A supplier audit is recommended and required to ensure the supplier is able to provide the services required with all the necessary documentation. This audit includes the verification of quality management system, standards, tools used, programming standards, working conditions, market reputation, development

methodology, customer support, and change management, etc.... Audit reports finding should be confirmed and verified. Depending on the audit results the supplier / vendor may be asked to reply to the audit observations and findings.

Legal requirements: Whenever external service providers are involved, legal contracts, service level agreements (SLA) should be incorporated and assured that regulatory requirements of the company are confirmed.

Functional specification - FS: The FS provides details of what the system should do to satisfy user requirements. The functional specification is termed as a preliminary functional design by identifying any constraints or potential deviation from the planned requirements. It should answer what the system should do and how it should do it? It explains how each feature of the system functions.

Validation strategy planning: The validation strategy planning is used to define the validation responsibilities, plan, strategy and approach selected, and the acceptance criteria. However, for smaller systems this phase can be replaced by a validation master plan. Final validation report is actually based on the validation strategy planning.

Design specification - DS: The DS translates the requirements of URS into a technical solution. Both developer and user involvement is required to facilitate this phase and a detailed review during the project development phase is highly recommended to maintain the design methodology. The DS includes functional, structural and technical design depending on the system size and complexity with detailed documentation. It explains how the system is intended to function or operate.

Implementation & testing: The purpose is to assure suitable implementation of the system components (hardware, software, etc...) depending on the size and complexity of the system. Proper documentation including development tools is required at this stage. Testing is a sensitive issue to provoke failures and to maximize the confidence that involves certain limitations depending on the goals. Testing helps the reliability and involves source code review, or peer review to identify any error, access and verification of the codes with applicable coding standards. To evaluate the system performance for user

expectation, end users are required to perform user acceptance test. A review of the user acceptance test results before a system installation on operation site should be done in order to satisfy the requirements. If executed test plans and test results are verified, organized and documented, significant qualification workload can be reduced. Traceable records among URS, FS, DS, and testing should be maintained at this stage in order to move for effective qualification.

Qualification: The qualification covers several steps including installation qualifications, operational qualifications, and performance qualifications, however, depending upon the size and complexity of the system these steps can be carried out in single stage. The identification installation and operational qualifications usually are based on the system's functionality.

Installation qualification - IQ: The IQ ensures that the system has been installed according to the predetermined design criteria and as it has been specified and setup in compliance with the requirements of both parties (manufacturer and user) and the complete documentation is available to prove this and for the users. Usually installation involves: checking that all the major system hardware, software, tools, peripherals, user manuals, reference documents are readily accessible and a regular maintenance program along with a back up in place.

Operational qualification - OQ: The OQ of the test system should be completed with complete SOPs (Standard Operating Procedures) and personal training before launching OQ. The OQ is carried out as a documented verification to verify that the system is in optimal working conditions including all functionalities and process operations, involving security access and backup facilities according to the pre-defined specifications. The OQ should be performed in a test environment when possible. After test execution, a review report with expected and achieved results, deviation found and conclusion must be approved to commence PQ.

Performance qualification - PQ: The PQ is documented verification to ensure that system operates throughout all operating ranges according to the requirements (stable system, operational documents in place, trained personnel) over a pre-defined period of time and is in compliance and the results are in

accordance to the expectations and in its actual use environment. System stability through continuous operation for a significant amount of time should be confirmed. This allows the encountering of a wide range of conditions to verify any error or fault in the system that do not appear in normal activities.

Standard operating procedures - SOPs: Approved SOPs must capture the details to standardize the validation procedure performance. Departments charged with abiding by or following these SOPs must first be trained against these ones. SOPs may include system operation, backup, restore, security, data handling, change management, disaster recovery, training, etc....

Training: Training is one of the essential elements for any successful validation. All concerned members (users, developers, persons involved in development, validation, maintenance...) of the validation project must be trained. Training records must be documented and maintained. Training plan should be used to manage the development of staff, and subsequent training should be conducted in accordance with approved procedures [354]. Training should be performed in a test environment in order to avoid any undesirable effects on the system. Typically, the training initiates within the validation group. It is essential that the lead validation resource for a given validation project initiate, facilitate, coordinate, and/or communicate the need for resource training [264]. Training must be provided on an ongoing basis to achieve the employee's full potential in validation process. Training enables organizations to implement validation standards in a way that could not be accomplished by organizations without timely trainings sessions. Training can become a tool to assist employees in coping with QM implementation problems. Validation practices cannot be successfully carried out in the absence of adequate training.

Final validation report: A review of all activities is done after PQ to perform a final system release verification, data transfer plan if any, to assure all deliverables identified in the validation plan and to sum up the completion of the validation cycle via the final validation report. Based on a positive conclusion the computer system can be released for use [111].

Change management - CM: Any changes to the system must be thoroughly documented and managed by a change management process. The CM verifies all impacts of the proposed / planned change on the system before that change is done. The CM defines the complete set of processes employed for tracking all changes to systems, applications, and environments defined by a respective pharmaceutical regulatory conformance and to manage systematically the effects of change. The changes are evaluated in order to decide the extent of validation required by the implementation of the change. Details of CM are presented in the next section.

Maintenance & regular review: The purpose of this phase is to assure the optimal use of system by properly maintaining the validation until the system is decommissioned. Periodic reviews should be performed and documented including SOPs, security, access, change management, backup files, training record, etc....

Decommissioning: The decommissioning is done to retire a system after completion of its intended use and when there is no more required use a proper procedural method to keep in mind its impact on the rest of the system.

The CM process should be used to track all changes related to the system's decommissioning and to avoid any impact on other systems. Updating of disaster recovery plan (DRP) and deactivation of the SOP if applicable are equally recommended. It is estimated that only 15% of organizations have an attested and effective DRP plan [329].

5.6 Roles and responsibilities for CSV

It is the top management responsibility to ensure that all relevant computerized systems are validated according to the organization policy and regulatory requirements. The organization must have the clear policy and means to make the system validated and maintained through formal organization procedures. Along with the planning and monitoring validation activities, all validation activities should be reviewed. The completion of validation activities should be documented to provide all necessary information. *Table 5-1* describes the responsibilities that can be related to the validation of a computerized system.

Roles and responsibilities will vary between organizations and there is no fix role to lead the validation process.

Function	Responsibility
The validation team is responsible for	All validation activities performed within a project, including the validation strategy and documentation; Leading the validation; Obtaining, preparing, and/or review the validation deliverables (protocols, reports, etc.); Coordinating and performing all system qualification tests.
The Supplier/ Vendor of the system is responsible for	Specifying, designing, creating, and testing the computer system in accordance with a quality assurance system; Preparing functional specifications (if applicable) and the entire technical documentation (including the user manual) of the system; Defining and performing the unit tests or integration tests or the FAT (Factory Acceptance Test).
Quality Assurance Team is responsible for	Defining the validation methodology in accordance with applicable regulations; Providing guidance and assistance for the implementation of the validation methodology and preparing the validation deliverables; Performing suppliers' audits; Reviewing and approving all validation deliverables in order to make sure that the documents are in compliance with applicable regulatory requirements and with the organization procedures; Performing internal audits.
System Owner is responsible for	For the compliance of the computerized system and integrity of related data; For assuring that a validation team is in place and that the required documentation is created and maintained and that the changes to the system are managed and controlled; Ultimately, the system owner is responsible for the validation of the system and for maintaining its validated status. The system owner must be able to present the validation file and the change control file to the health authorities at any time.

Function	Responsibility
The Users as members of the validation group is responsible for	Preparing the user requirements specification; Performing qualification tests of the computerized system; Preparing and issuing SOPs and instructions for the use of the system (if applicable).

Table 5-1: Function and responsibilities for key validation activities

Throughout the validation process a package of documentation should be maintained that contains the required working documentation of the process. The validation plan and validation reports are often some of the first documents to be examined by GxP regulatory authorities inspecting a pharmaceutical or healthcare facility. Key validation documents must include change control records [354] as CM is the required key operation for the information system of pharmaceutical organizations [162]. Attempts to structure the formidable problems of validation have led to standardizing and formalizing documents and validation techniques and to incorporating the documentation function into the validation life cycle. The key elements and documents of the validation are indicated in *Figure 5-2*.

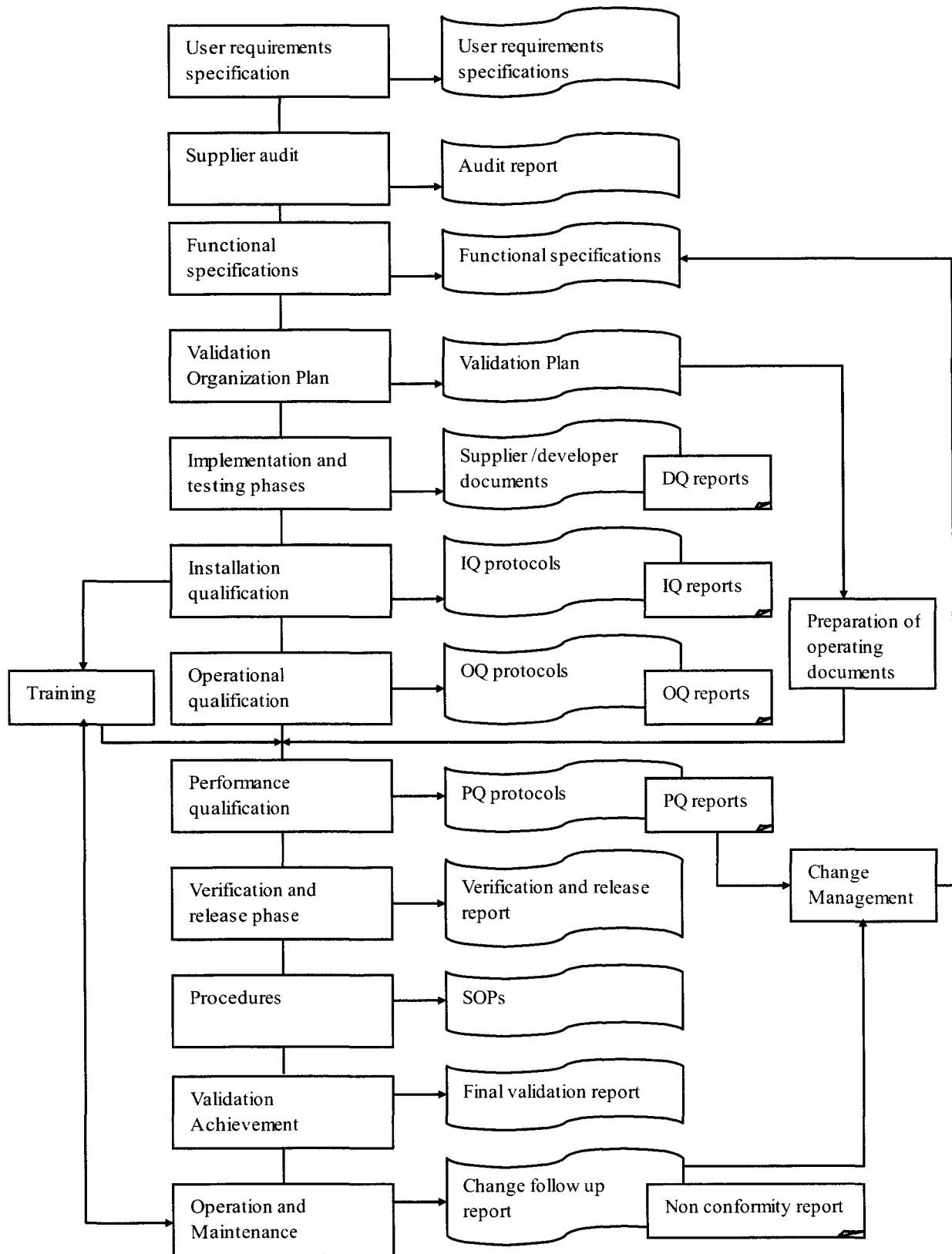


Figure 5-2: Key validation deliverables (procedures and documents)

The validation experts of the future must be able to cope with the environment that is system oriented and in compliance. The implications of

validation are great when applied to the information system. The purpose of the validation of a computerized system is to make sure that the system and its use are in compliance with applicable regulatory requirements. It provides guidelines to assure that the system is in compliance with all functional, reliability, integrity and security requirements and its operation is under control, and any changes of such systems are well managed through change management. Validation should be regarded as part of an integrated concept to ensure the quality, safety, and efficacy of pharmaceuticals [98]. The validation life cycle sets forth a logical order for the events; that takes place in the validation of a system and it encompasses problems and risks that occur during the validation of a system.

In presenting this CSV methodology, an approach is defined with the responsibilities involved in the validation of computerized systems used by pharmaceutical organizations in a regulated context (GxP, BPx). In order to obtain the maximum benefit from the CSV, the respect of procedures, organization and company's commitment to support and maintain the system is essential. The system owner, quality assurance and validation teams and users mutually play an important role to make a validation successful. Once a computerized system is validated, there is a constant need to manage change. We describe change management in the next section that was a critical part of CSV.

5.7 Change Management (CM)

Various parts of this section were drawn from my previous publication in the *IEEE-CCECE* Conference in Ottawa, Canada in 2006. The article concerns the CM in computerized system for the pharmaceutical industry.

The change management process in most organizations faces enormous pressure. In the cluster of a large number of heterogeneous changes in information systems, pharmaceutical organizations recognize the need to align the process of change management to properly validate the changes and their impact on their information systems. Change management is closely connected with all project processes and functions, which are exposed to changes [366]. Rigorous regulatory requirements are being driven to concentrate on change management practices in pharmaceutical organizations. At the same time, the volume of contents to manage changes that needs to be captured, dealt with, and maintained in support of the

change management requirements continues to increase. According to leading analysts, up to 80 % of IT changes are delivered late due to changing business environments [393]. Projects intended to implement significant changes in the way an organization works seldom turns out as expected [41]. Moreover, the FDA binds the pharmaceutical organizations to prepare well the change management process. Change Management is considered to be more comprehensive, including not only changes to procedures but changes to equipment, specifications, etc. Change Management is more conducive to enable change to be made in a risk based manner taking into account the integral nature of pharmaceutical systems [222]. Where there is risk, there is an interplay between dysfunctional certitudes and incertitudes that can threaten the system. Not all certitude and incertitude is dysfunctional as such. But, for organizations in “QM Implementation” context where there is risk, there is also a need for timely communication to inform, and training to reassure dysfunctional incertitudes, and to shake up dysfunctional certitudes.

Over the last decade, many organizations have installed major information systems in their health care organizations [181]. There is an increasing demand for the systems that matches real user needs to manage changes and to document all relevant processes. Information systems are now considered central to most changes in health care [210]. With the changing business needs, pharmaceutical organizations are focusing on process-based change management to better manage their CM activities. The discipline of change management deals with the way of developing a planned approach to change. Typically, the objective is to minimize the disruption to the normal flow of the activities and to provide an efficient means of tracking changes to new and existing systems, applications, and environments within the information systems. This helps to maximize the efforts of all people involved in the change process and to minimize the failure risk of implementing the change and the impact on other related systems. Change management ensures that its CM process does not severely alter the system’s functionality, integrity, availability, stability or security, etc... by involving an excellent documentation to track all approved and planned changes.

One of the biggest challenges facing the pharmaceutical industry is how to manage and maintain the huge volume of documentation that is generated during

the lengthy and complicated process of developing a new drug [64]. An effective CM process enables centralized documentation of the completed changes, establishes responsibility and authority, and closely controls the developmental and / or validation environment prior to production. Any changes to the system must be thoroughly documented and managed by a change management process. In order to ensure that changes will occur, the basic awareness first needs to be converted into motivation through reasoning, and then into action through planning [132]. For the decision-making process, change management plays an important role in managing a change.

This section addresses in a non-technical way, change management methodology of an information system. The remainder of the paper is organized as follows: We begin with defining the change management framework, which is followed by a description of the CM lifecycle. Then we present the strategy to implement better the CM proposed by the conceptual framework of this thesis. Finally, we present our conclusion after the discussion.

5.7.1 CM Framework

The process of changing information systems in accordance with defined rules is termed as the “change management” process. These rules ensure that changes to a production environment:

- accomplish their intended use
- do not adversely alter the system’s functionality
- are adequately documented
- are easily tracked
- do not compromise the stability and security of the concerned production information systems
- are officially approved prior to implementation

The CM process provides a tracking method for changes to the information systems and environments. We will address changes from the time a change is initiated to its evaluation, and ultimately, to implementation. Each CM submission is evaluated based on several categories and will be the criteria for how change will be processed. In defining a change management framework, there are several definitions based on four major types of changes (minor, like for like, emergency and major) that we will use to describe all changes that might be considered.

5.7.2 Definitions

Minor Change: Minor change does not have the potential or major impact to affect the system. This can be defined as a planned change of an application and / or hardware component that has minimal impact on its environment and does not disrupt hardware, software, data, etc. Examples are bug correction, adding a component (hard drive, CPU - central processing unit, etc), adding functionality that does not alter the previous objective of the application, etc).

Like for Like Change: This change does not involve a significant (qualitative) change to affect the system in any aspect. It may be a replacement or change to equipment, system or a hardware component that contains the same / equivalent characteristics, dimensions and specifications. Examples can be replacement of CPU or other components, power supply, etc.

Emergency Change: Change management should avoid changes in the middle of a crisis [210]. However, sometimes, there is an urgent need of a change having the capacity to severely affect the system and that could be potentially harmful if not recognized urgently. It involves any unplanned changes, or correction of a failure, of an application or hardware component that, disrupts the continued operation, needs to maintain a competitive advantage and needs to maintain public safety when there are no viable alternatives to solve the situation. An emergency change is driven by an immediate business or technical requirement, with no advance warning, with a clear and appropriate justification. .

Major Change: Major (qualitative) changes start at the conceptual level [114]. Major change can be defined as a planned change to an application or a hardware component that could impact on data integrity, system security or system

availability in a manner that significantly affects the business. It is often necessary for a customer to re-qualify in their process a component, which has undergone a major change [10]. Major changes may involve several or critical systems, and can disrupt hardware, software or data in case of an unsuccessful effort. So a detailed and formal planning, and decision making, is required to control any significant impact on business.

5.7.3 CM Process

This section attempts to make a modest contribution in the phases of CM by focusing - through multiple dimensions - how people can make a change happens successfully in the information systems designed to have varying levels of structure. All these phases contain key information required to manage the change. However, depending upon the size and complexity of the system, these steps can be carried out in fewer steps. Emergency changes can follow the route suitable to business needs and priorities. Several areas can be identified to cause a change including impact analysis, risk analysis, planning, and notification, implementation and post implementation review [277].

The CM framework contains key information from which the CM request evaluation takes place and determines how a change will be processed. It includes:

Proposed change description: why and what needs to be changed? (list of all concerned activities undergoing change). It involves identification of the system impact with the process owner. All changes must be documented thoroughly and contain key information from which the evaluation takes place and will determine how a change will be processed.

Change category justification: It can be based on three dimensions along which the change may be classified and reasons for major, or minor or emergency, or like for like change.

Impact analysis: Impact analysis includes all concerned areas, systems, documents, GxP, etc.... can have possible impact by the change and how one will manage in order to support the change.

Risk analysis: Areas, systems, documents, etc. that can be affected by any possible risk must be identified and a clear planning to avoid its effect should be proposed. For each risk, the probability of occurrence and the impact to the project should be classified as low or moderate or high risk.

Action plan: How will the change be carried out? (list of all the concerned activities and / or deliverables to support the change).

Manage change: Depending upon the nature and classification of change, suitable actions and recommendations on the proposed action plan must be followed.

Monitor change: Keeping track of the identified problems to evaluate the change process to assure smooth change process.

Implement to production: Manage change to production in case of successful attempts and validate the change. Verification of all actions against the implementation is necessary.

Close change: All the approved activities listed in the action plan must be completed and reviewed before a change is implemented and completed. Based on the above explanation, we can envisage a CM process. It can be used to track all changes related to the system by observing any impact, risk, priority on other systems, etc... The above explanation is useful to initiate a change in order to cope with it during all phases until the end.

5.8 Discussion

Computerized systems are constantly changing so there are always a number of things to learn about new and constantly improving technology that is necessary to compete in the business market. Computerized systems executives should focus their attention in encouraging employees to actively participate in validation activities and to provide them with appropriate and timely training to actively participate in the validation process. Several studies show that the lack of communication, underestimation of the complexity, unclear defined role of the organization to manage change, lack of technology can cause failure to information system [187] [221] [222]. These factors can play the same role in

affecting the change project and there is a need to clarify the scope, and the overall approach of the proposed change. Like any QMS, major focus of CSV remains on the quality elements which are top management, employees, quality strategic planning, customer focus, process management and communication-to-inform process. For change management few factors were considered important. These include effective planning, training and clear communication-to-inform process.

Effective planning: CM fosters planning and focuses on team efforts; failure to achieve planned results indicates a failure in the change process. Cooperation among different teams is necessary to achieve the goal.

a) Clarify short / medium / long term plans to ensure appropriate focus and direction. Encourage and facilitate discussion in achieving the goals.

b) Involve others to create a long-term vision of planning to align organizational strategy in a broader business context.

c) Set parameters for team members to get the job done according to the defined objectives in terms of ultimate outcomes.

By deploying enterprise CSV with a strong CSV foundation, organizations can reduce system downtime by providing a consistent, managed CSV process and reduce risks and to improve satisfaction levels. One must establish a viable process from which one can manage major changes.

Training: Employees learning and continuous improvement are now considered essential for an organization to remain competitive [315]. According to Kraiger (2003), successful organizations are thought to invest more in training and development than other organizations [181]. Training is defined as the systematic acquisition and development of the knowledge, skills, and attitudes required by employees to adequately perform a task or job or to improve performance in the job environment [204]. Timely and well planned training is an effective commitment to fostering long-term growth, with particular attention paid to how their skills and talents can best be utilized to cope with the CM process and business needs [162]. Top management involvement will make sure that CSV documentation and procedures are fully understood by the concerned employees.

There are standard questions that can best be answered through training (clear instructions of how things should be done, reassure personnel who are confused by the change [coping with uncertainties], encourage personnel to question certain aspects of their practice [shaking up targeted certitudes], etc.). Training is a way of learning for employees (Tharenou et al., 2007). As the knowledge of employees increases, it becomes easier for employees to interact with validation activities because related QM knowledge is understood by these employees. Thus, training facilitates the QM implementation of CM process.

a) All personnel trainers should optimize their technical skills and work on a style that compels and motivates the team to better understand the validation and change process in order to participate in the process.

b) Provide state of the art knowledge in CSV and CM process in order to enhance personal capability to contribute to the process.

Clear Communication-to-inform process: CSV team should maintain clear, two-way communication regarding the procedures so that everybody can follow the CSV process.

a) Improving the quality of information provided for validation and change can facilitate the CSV process. Validation activities can not be successfully carried out in the absence of communication-to-inform function.

b) While presenting the proposed change, one needs to understand the rules: a clear understanding of why writing for the change is different (impacts, risks, priority, etc) and an ability to verify all aspects to exploit its benefits and avoid its pitfalls [162]. Keep the team informed of events, decisions, or changes that may impact them.

The proposed methodology was presented with an aim to focus on a general approach to CM process that can address several needs without addressing the technical aspects. It must be recognized that the change management of computerized systems is highly important. Nevertheless, a well-defined CM plan can formalize the CM process, the associated strategy, the responsibilities and the acceptance criteria applicable to an information system including risk analysis,

impacts, etc. The approach presented in this section can help to avoid some of the common pitfalls in CM of the information system. The real challenge is how we plan for and document the CM activities for the system in order to better implement the approach presented in the least possible time and resources.

5.9 Conclusion

Once the final validation report is issued, the system should be maintained and a regular review is required. The system owner is responsible for the operation and monitoring of the system. Various activities can be helpful for a smooth operation including:

- All the non-conformities of the software or equipment should be tracked with non-conformity forms in accordance with CM procedures.
- All system changes must follow change request addressed through a CM procedure and follow-up form.
- The functional specifications document must be regularly updated to integrate the changes made to the computerized system.
- All the changes in the software and equipment must be reported in the computerized system logbook in accordance with SOPs.
- Qualification tests must be planned either following any change to the system or routinely.
- Audits may be performed at any time by quality teams to make sure that organization rules are followed, and to check that the system is still under control.

A clear approach to validation can help minimize the communication gap between the validation specialist and the system user. The validation process should include the general scope of the system including high level design features, the teams responsible for the validation, a clear timeframe, and a brief summary of other supporting documentation that need to be addressed in order to use the system [54].

As can be seen, there are many stages to go through before the system is fully operational; thus the acquisition of a CSV must not be undertaken lightly. Validation at the end of the life cycle must be complemented by verification at each stage, as it is a more cost effective approach [213].

Validation is highly dependent upon the effectiveness of the planning that goes into it. In many cases, validation may require considerable resources, in terms of time, money, and specialized personnel, so getting it right and getting it done on time is crucial. An organized well-planned validation increases the reliability of computerized system thereby decreasing the compliances problems and increasing the company's confidence to fulfill the requirements of regulatory agencies. A better understanding of validation of computerized system is of high importance and will continue to play an important role in various aspects: to minimize risk and enhance compliance, overall effectiveness and efficiency, system impacts. Obviously, achieving validation of a computer system involves developing, maintaining and releasing computerized systems throughout its lifecycle and assures that the system consistently meets its specifications, thus making it worthwhile for its intended use. The cost of validation is determined by the time spent on documentation, development of protocols and Standard Operating Procedures (SOPs) and the time spent on actual fieldwork, data collection, and analysis [339]. It is interesting to note that a good rule of thumb is that total validation costs may run from 4% to 8% of the total project cost for typical pharmaceutical plant expansion projects [136]. Some researchers have experience with the system where validation reduced maintenance support costs by 75% [388].

CSV goes through a number of stages from the time they are conceived until decommissioning, that is a life cycle. The validation life cycle concept is useful because it provides a disciplined approach for the development and operation of the CSV. The tasks identified as belonging to a specific stage of the cycle are important as they contain coherent framework for organization of the validation process.

5.10 Summary

This chapter review primarily focused on the QM standards that are dominant in pharmaceutical industry and important for our case study two presented in chapter seven. This chapter presents the validation approach required for the computerized system in the pharmaceutical industry. The chapter provides an overview of the validation activities, responsibilities involved and major elements to validate a computerized system in the light of a regulated context (GxP, BPx). We define the approach of change management involved in the validation of computerized systems used by pharmaceutical organizations. The overall purpose of the review presented in chapter two, three, four and five is to identify and arrive at appropriate elements of QM in organizations. Literature review from the above chapters helps the understanding and construction of communication-to-inform process, quality management, QM standards in organizations (ISO 9001 – presented in chapter four; CSV – presented in chapter five), to observe QM process in industry. The purpose of next chapter is to address the issues presented in conceptual framework (chapter two, three and four) for the case study conducted in *Toyota Motor Manufacturing France*.

6 Case study 1 – *Toyota* Motor Manufacturing France

6.1 Introduction

Case study observations about implementation of QM in *Toyota Motor Manufacturing France* and understanding of QM process had an important role in this research. The conceptual framework (presented in chapter two, three and four) helped me to understand the key concepts for QMI and case studies were conducted to examine the implementation process while working very close to the industrial departments in the organizations selected for my case studies (*i.e.* case study one: engine assembly line, case study two: quality and validation department, case study three: maintenance department). This chapter presents an overview of the methodological perspective for the first industrial case study. Section 6.2 describes the research methodology adopted in this study: sampling and demographic information. The section describes the research strategies adopted in this case study. Section 6.3 presents the case study organization description and its processes. *Toyota* Production System (TPS) is presented in this section. Section 6.4 presents the evaluation of QM elements for implementation. Section 6.5 describes the evaluation of QM implementation phases. Section 6.6 presents the key elements and improvement plans after evaluation. The conclusion of the case study is presented in the section 6.7.

Quality has become a key concern to organizations, not only because of the growing importance of the quality system, but also because of the multitude challenges. The goal of this industrial research study is to understand and analyze the implemented QMS in the Engine Assembly Shop (EAS). The study provides some significant results and ways to promote quality activities by emphasizing quality at all stages by involving everybody in the company, which can help solve problems and denote excellence. While working in *Toyota*, my job mainly moved around defining, evaluating and confirming QMS for ISO-9001 for the EAS. The approach specifies several routes through which quality awareness culture (refer to chapter nine) about quality issues impacts on people working for the QMS.

6.2 Methodology

This section provides the methodology for this industrial research project. A brief discussion of the sampling frame, demographic information, assembly line details, research strategies are provided.

6.2.1 Sampling

The automobile industry in the North of France was selected for investigation due to its position as one of the most important industrial centres in France, as well as for practical reasons as I was settled in the region at that time. Moreover, some years ago, I worked for three years in the industry and had good working knowledge of QM, this also helped me on in this study too.

The EAS was composed of 90 people including 74 team members (TM) with their 14 team leaders (TL) in charge, along with two group leaders (GL) (who were responsible for six TL (refer to *Figure 6-2* for organization chart of EAS) who were involved in the QM implementation for an ISO 9000 project in the EAS of *TMMF* in France.

6.2.2 Demographic Information

In the EAS, 99% of participants were male. This gender homogeneity was not unusual since most of the people (TM, TL and GL) working on the engine assembly line are males in the industry. All members have been in the assembly line for at least six months. The lowest educational level of the participants was a High School diploma (equivalent to Lycée in France). All participants were French except three who were of Senegalese, Taiwanese and Moroccan cultural origins.

6.2.3 Case study process

In the beginning, I presented the aim of conducting the case study to the management of the EAS. After the approval of the Human Resource (HR) department, EAS management and HR department were asked to find a research

coordinator to help me to conduct the study in the EAS. Then, the Assistant Manager of the EAS was asked to give a general introduction of the assembly process, production activities, organizational structure, etc. Then, I planned a quick guided visit of the organization in order to understand the working environment, production activities, major processes and facilities. Afterward, I started gathering relevant information about the EAS with the coordination of the Assistant Manager (EAS). This induction session was very beneficial in getting information about the organization (history, *Toyota* Production System, current QM implementation practices, annual sales, targeted area for sales, overall business performance, organization's rules and regulation). The management includes EAS coordinator (in *TMMF*, it represents a Japanese advisor who assists the department on technical and non-technical issues- equivalent to director), manager assembly line, assistant manager EAS, quality manager and quality specialist to discuss QMS implementation issues in the EAS. (Refer to *Figure 6-2* of the organization chart of the EAS for explanation). Afterwards, an audit was conducted to observe the practices and the strengths and weaknesses of the organization's current QM implementation, and thus several areas for improvement were identified. A detailed discussion with management was held in order to finalize the audit report. Based on the weaker areas of the organization's QM implementation, an improvement plan was formulated with all the concerned teams along with deadlines to meet the action plans. The improvement plan consisted of a set of improvement plans and removal of existing non conformities. In order to make the improvement plan more practical and applicable, the quality manager was constantly contacted, and the EAS coordinator was asked to be involved in its development. Finally, based on the result obtained after various observed audits on a regular basis and evaluated from the EAS management and improvements were shown, I was then able to make a final case study report. QM elements and QM implementation are presented in section 6.6.

6.2.4 Case study description

The basic goal of the case study was to offer an example of QMI in order to observe the QM elements and QM implementation at the grassroots of factory

floor. The observations were used to developing a model proposed in the chapter of QM modeling. The case study organization was asked to support me in accessing and evaluating the organization's quality elements and the QM implementation process. In this way, I proposed to establish an improved action plan after identifying the weaker areas. If this proposed plan is accepted by the top management to implement in their organization, it can be inferred that the observation for QM implementation for improvement are applicable to this organization.

As discussed earlier in chapters two and four, top management plays the key role in QM implementation processes. Top management is responsible in effective implementation of QM. Through detailed discussion among ourselves (manager of the EAS, HR Manager and myself), it was observed that the top management of the organization was dedicated to providing sufficient support for the case study to be conducted in the organization. This seemed to be an important step in advancing towards implementing QM. Therefore, top management commitment paved the way for me to acquire the necessary information to conduct the study, in addition, to approaching all the relevant people. Without this step, the study could not have been conducted in the organization.

A team was formed to implement the QM for ISO 9001, in which I played the role of "coordinator". The formation of team was composed of five members including me, one of the group leaders, assistant manager, manager of the EAS, and the quality engineer. The quality engineer was from the quality department who helped me in conducting the study and explained some history about QM implementation in the EAS. I asked the quality engineer to provide details with relevant quality information and support from his department in order to make the study successful.

Another important step was to understand the quality vocabulary and language used in the EAS. Each organization has a set of vocabulary that is used in order to convey the organization's standards. All people working for quality need to absorb this vocabulary. This is equally important in communicating various tasks. I participated in several training sessions in order to understand the TPS terms used in the organization. The objective was to attain a fair understanding

about the organization's vocabulary that helped later in promoting common quality terms in QM implementation. This is a continuous process and always needs to expand its effects within the whole organization so it can keep the same perception for all its employees.

I used the assessment method to observe what is happening in daily use. The evaluation of the QM system was seen as observing daily routine activities in order to make improvements in these activities. Thus, the evaluation was considered useful for the judgment and improvement of everyday activities. The evaluation phase was done to evaluate the QM elements and implementation in the organization and to prepare for the ISO certification audit. Then, various internal audits were observed to improve the evaluation process and to obtain an improved understanding of the existing QMS of the organization. With the help of the evaluation step, weaker areas were identified for improvement.

After evaluation, a report was established to present weaker areas with improved action plans. The main aim of improved action plans was to improve the QM implementation phases. At first, a list of identified weaker areas was bigger than the final one. The list was further reduced to make all the action plans for improvements feasible due to time and resource constraints in the organization (including resources available, the impact of potential improvement on the organization's business and process activities). Moreover, an evaluation report and a proposed improvement plan were revised with the QM implementation team to better define deadlines and responsible persons to implement the proposed actions. In addition, several team leaders were also involved in order to better understand weaker areas and make the plan robust. After brief discussions, the proposed improvement plan was recognized by top management and an official acceptance was delivered to deploy further actions.

6.3 An introduction to the organization

The case study organization was located in Onnaing, North of France, and was among the world's key organizations in manufacturing cars. Its market share ranked third in the last few years and second in the World since 2006. The organization had been implementing QM for a long time and obtained ISO 9001 certification in 2001 (except the EAS). Due to its well known production system,

the organization was reputed as a world class organization. A brief detail of *Toyota Production System* is presented in the section 6.3.3. *TMMF* had fixed assets of 150 M€ and occupied a piece of land with an area of 230 hectares. The organization had more than 2500 employees in 2002-2003 in the plant including 10 % of people involved in supervision or management activities. Its organizational structure and people working in different departments are displayed in *Figure 6-1* (light blue color indicated the top management of the EAS). *Figure 6-2* displays the organization structure of EAS. In *Figure 6-2*, quality management indicates my position in the EAS during the industrial project.

The organization started the EAS in April 2002 whereas the rest of the plant started production in January 2001. The decision to start the EAS was taken to reduce the transportation costs of the car engines from the organization's other site located in the UK. The decision was also helpful to ensure the autonomy of the site and to reduce effects of difference of currency zone and additional taxes. In early 2002, the organization planned for the ISO certification for the EAS.

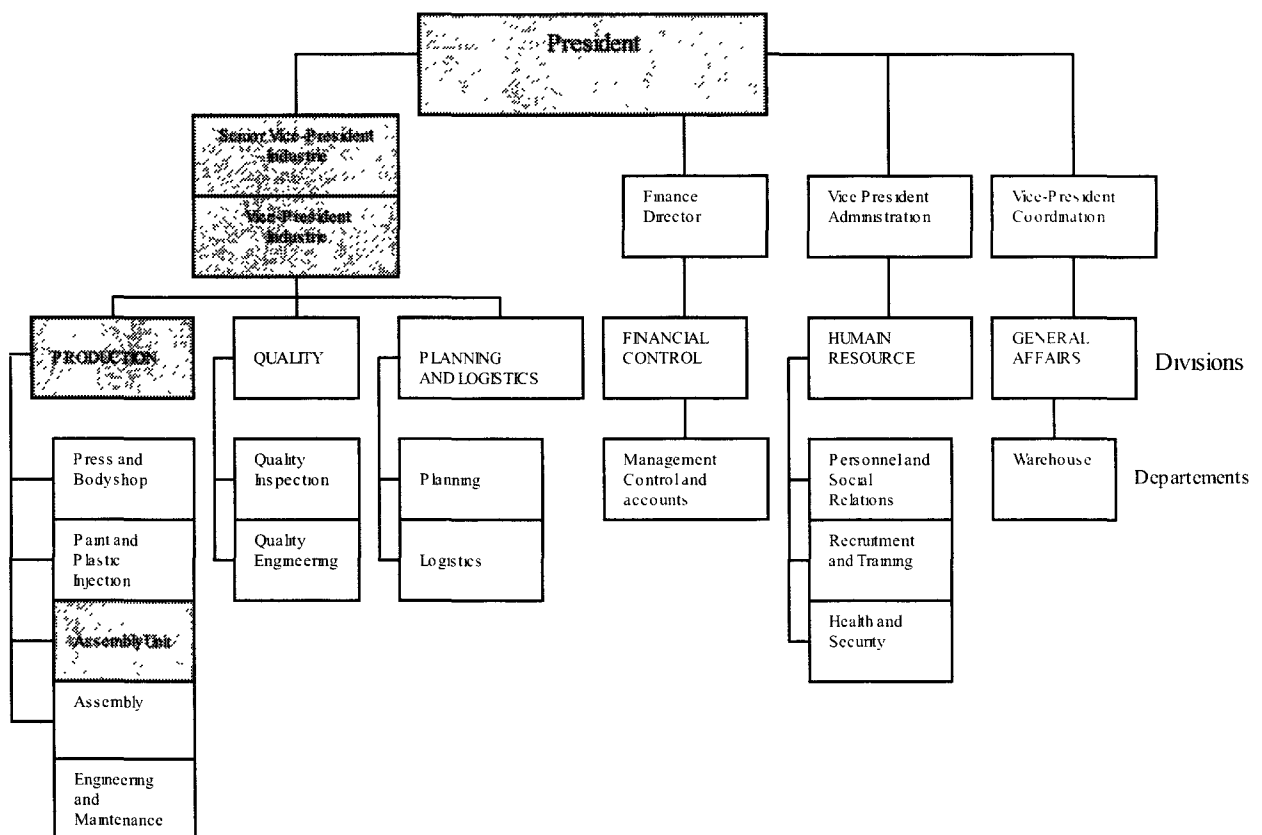


Figure 6-1: Organization chart of TMMF in April 2003

TMMF has six major division including production, quality, planning and logistics, financial control, human resource and general affairs. The production division was divided into five departments and EAS was a part of an assembly unit department, where I worked.

In the EAS, I worked with an Assistant Manager, Manager Assembly line, coordinator EAS, and EAS teams. I provided support to the EAS teams with the help of Group Leaders to deploy improved action plans. Quality department remained in contact through quality specialist and quality manager to prepare for audits and QM implementation. Details about EAS activities are provided in section 6-3.2.

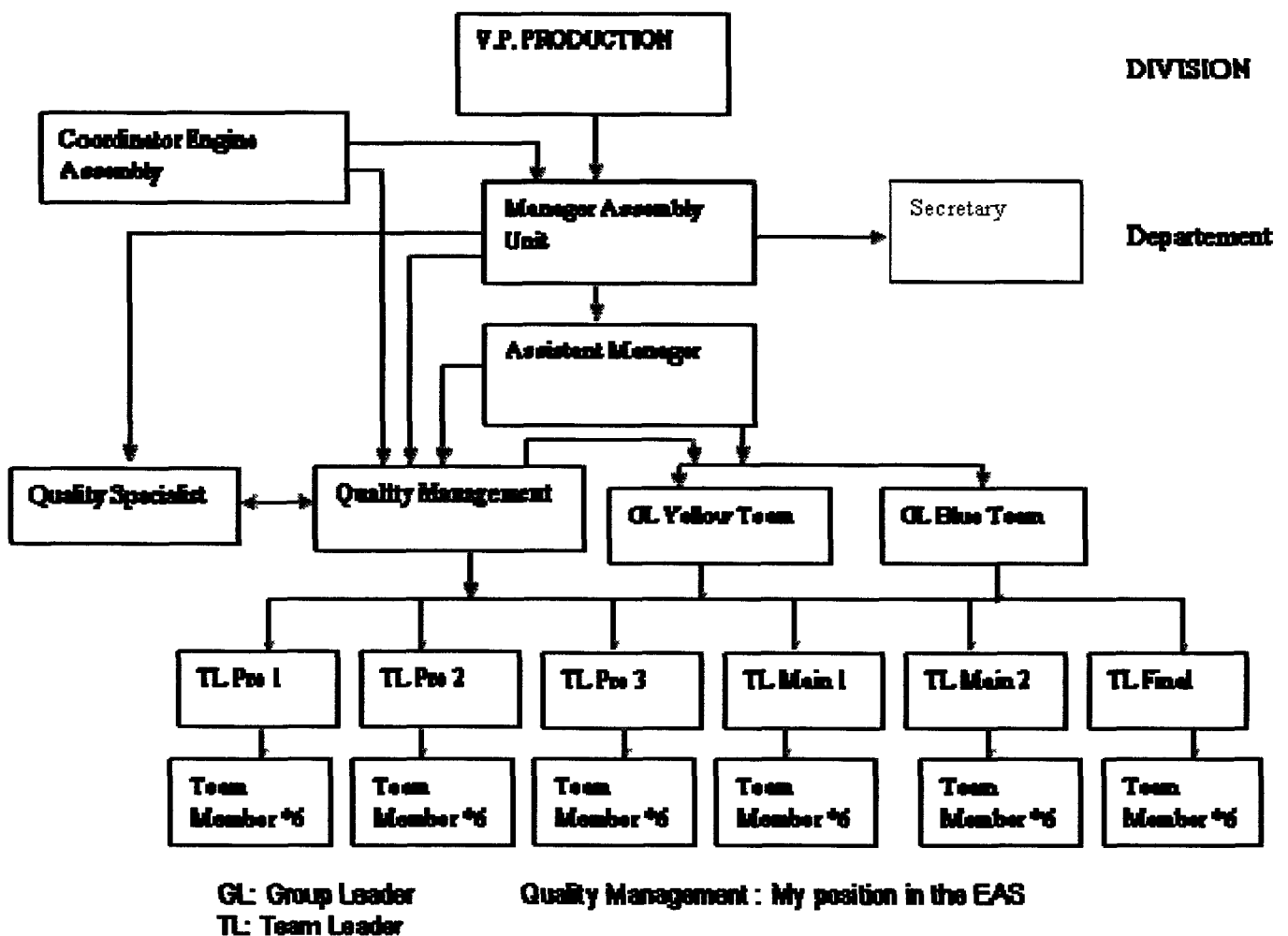


Figure 6-2: Organization chart of Engine Assembly shop at TMMF in April

2003

Before going into details, we present a short overview of this industry in order to put in context the study conducted in this doctorate.

6.3.1 TMMF manufacturing processes

Producing automobiles is an integrated, broad based operation. Each car is made up of more than 10,000 components which are themselves made of a wide range of material and types including glass, steel, rubber, electronics, ceramics, and majority of these are provided to the final manufacturer by outside suppliers. Moreover, assembly operations are human labor intensive. Reliance on people in the assembly process is high, and the number of production processes that require human labor has grown considerably with time. So a constant focus on humans is required in order to make the system run effectively. *Figure 6-3* describes major processes at the site of *TMMF* to manufacture the Yaris automobile.

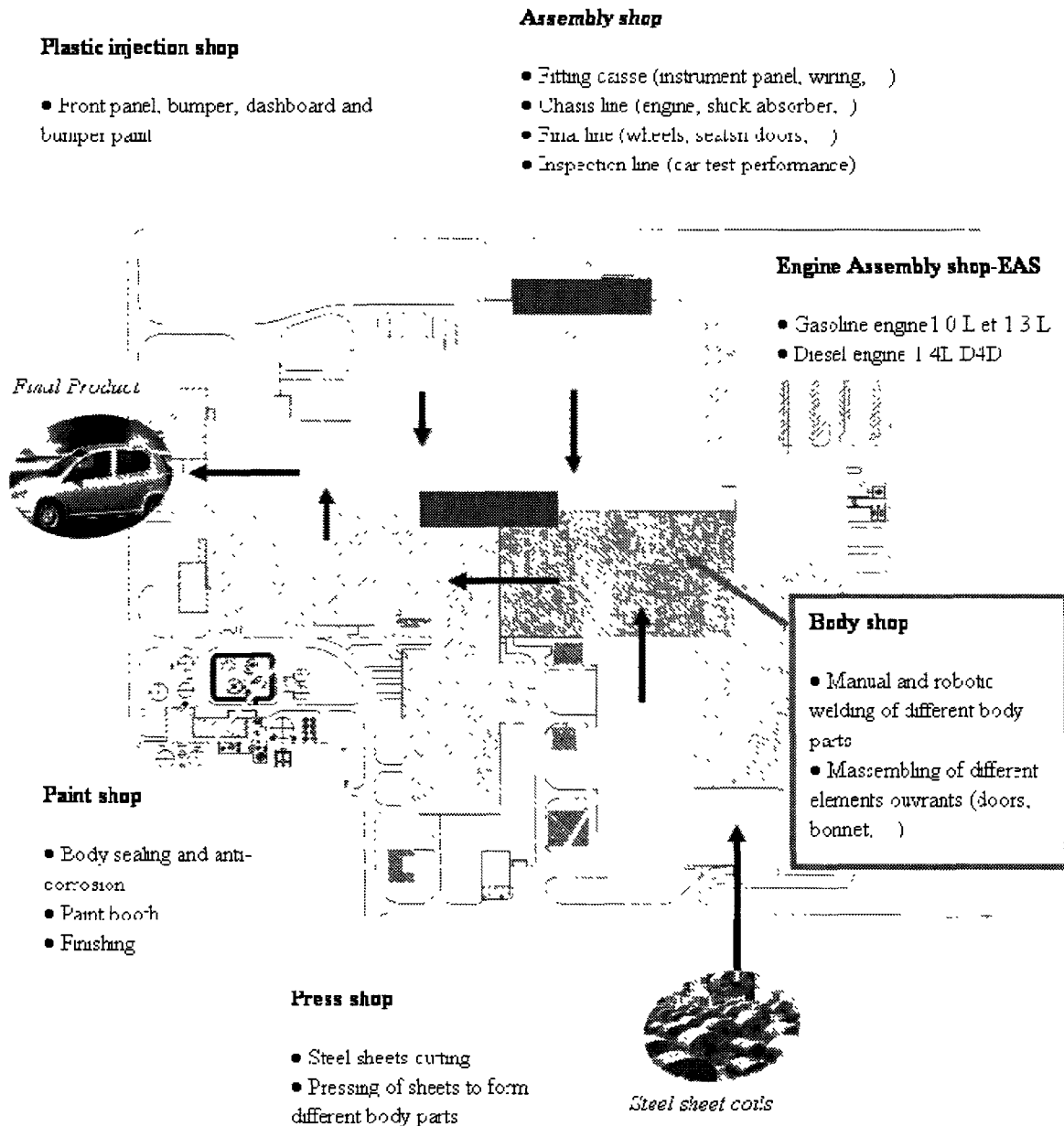


Figure 6-3: The whole plant in a glance

6.3.2 Engine assembly line description

Engine assembling is a delicate process and certain parts characteristics are confirmed during the process (*i.e.* verification of certain tightening torque, etc). Depending on the type of process being carried out, the inspection may lead to a 100 % or sample checks to verify that it meets all the requirements and standards that are defined by TMC in the quality check standards (QCS). Usually, the process stops at every 50 engines for one minute and is subjected to inspection of

all important quality characteristics in order to inspect (measured, visual, etc... depending on the nature of the process) the stability of the process and to note deviations if any. The control of these parameters is thus a key factor of the quality system of *Toyota*.

The assembly line assembled three types of engines, petrol engines (1l and 1.3l) and diesel engine (1.4d). The assembly line was composed of six processes with 32 operations for gasoline engines to assemble the whole engine. The assembly line processes included Pre 1 (engine block and crankshaft), Pre 2 (piston), Pre 3 (cylinder head), Main 1 (timing or distribution), Main 2 (injection and transmission), Final (finishing). Six teams deal with different processes involved in assembling the whole engine. For example, one process was to engrave the engine block. This process was composed of several operations including block preparation, oil pressure switch fitting, block number reading, *kanban* transfer, block shifting and rotation, typing the block number on the machine, rotation of block, mounting and protection of the oil filter. In this process there were some operations that one controls to check that the job done totally respects the values defined in the QCS. For example, the tightening torque of the oil pressure switch defined in QCS was (10.6 – 22.4) N.m.

The engine assembly floor was a part of the department "Assembly Unit", which was headed by a manager. The department was previously a part of the "Assembly" department, which was then divided into two departments to improve management. The resulting departments were "Assembly Unit" and "Assembly". The department "Assembly" was managed by another manager. The department "Assembly Unit" was a combination of the engine assembly floor, logistic and plastic section. The organization chart of engine assembly line is presented in *Figure 6-2*.

The assembly line works in the group of two teams with morning and evening shifts ("blue" and "yellow" team). Each team is composed of 30 TMs along with six TLs with a GL. In addition there are two TMs for the general shift. The total strength of the assembly line was 78 including assistant managers and managers. There were two GL managing the teams "blue" and "yellow" in two (morning and evening) shifts on alternate basis.

At each process, each TM was provided with an instruction sheet and guidelines that contained the necessary information and stipulates the differences in sequence from one engine to other. All TMs were advised to read it before performing an operation in case of doubt. All operations (stocking of screw, nuts, bolts, pieces, preparation of certain parts before assembling on the engine) which were required to do on the line was mentioned in the JES. The layout of engine assembly is presented in appendix 1.2.

6.3.3 Toyota Production System (TPS)

The *Toyota* Production System (TPS) is based on being "lean". Manufacture only what is needed by the customer, when it is needed in the quantities ordered. The manufacture of these goods is done in a way that minimizes the time taken to deliver the finished goods, the amount of labour needed, the floor-space required and does it with the highest quality, usually at the lowest cost.

The TPS is well known throughout the world. This production control system was established based after many years of continuous improvements, with the objective of "making the vehicles ordered by customers in the quickest and most efficient way, in order to deliver the vehicles as quickly as possible" [217]. It consists of two pillars, "Just in time" and "*Jidoka*" ("automation with human intelligence", see below). To simplify the above, we can say that producing with minimum inventory to lead towards the quality automobile produced in a timely manner with minimum possible lead time and lowest possible cost.

6.3.3.1 Just in time (JIT) or Lean Manufacturing System

This concept was founded through the contributions of Dr. Shingo Shigeo and Taichii Ohno of *Toyota* Motor Company (TMC) from 1949 to 1975. The basic element in developing JIT was the use of the Ford system to make the workers a more contributing part of the system. JIT manufacturing is based on planned elimination of all types of wastes and use of kaizen (continuous improvements) for productivity. It refers to producing and conveying what is needed, when it is required, in the exact amount needed. It attempts to manufacture with minimum or

no inventory, resulting in shortened lead time and effective savings in transport costs. JIT consists of the following operating principles:

- The pull-system – as accomplished by *Kanban*: One of the radical components of the JIT stresses on producing the right part at the right time in the right amount. It is the way of controlling the flow of resources by replacing only what is consumed and it prevents over-production and assures prompt and accurate dissemination of information. It leads towards elimination of excess inventory and synchronization of production where production is tied to processes closest to consumption. It shortens production lead time by the guarantee of synchronized processing throughout the entire manufacturing process. The Japanese word "*kanban*" means "signboard" and is a signaling system. If five boxes are used on the assembly line, five more boxes are put on the rack. If only one box is used, only one box is replaced. It is used to trigger the movement, and supply of items required. It refers to providing the communication of necessary information of parts used on the assembly line. It improves the inventory system and an accurate stock is maintained through *kanban*. If no parts are taken away, no further production is done and no more command for the part will be launched.



Figure 6-4: Kanban including details of part number, description, designated storage area, standard pack quantity, etc

- **Takt Time** or synchronized processing speed: It is time allotted for producing a part or a required task. It is the time necessary to finish a given amount of work. The time is calculated on the monthly production requirements basis and the operating time available in the month. It can be formulated as total daily operating time divided by daily production requirement. Setting exact Takt Time for each process is critical to make different components that together make an automobile on schedule, at the right moment. If each process ensures the respect of Takt Time, production will amount to exactly what is needed when it is required.

$$\text{Takt Time} = \text{Operating time per shift} / \text{Production requirement per shift}$$

6.3.3.2 Jidoka

Jidoka in Japanese is termed as "automation". However, in *Toyota*, it is referred to "automation with human touch" which means that when a problem occurs, the equipment stops immediately, preventing defective products from being produced or the ability of production line to be stopped in case of problems like equipment malfunctions, quality problems or work being late, either by machine which have the ability to sense abnormalities or by people working on these machines. Major advantages of the *Jidoka* include prevention of ignoring defects and equipment breakdowns. *Andon* is an example of *Jidoka* that is a colored coded display board that communicates machines abnormalities to the process supervisor or manager. Defects are stopped on the assembly line automatically and error handling is management in these cases. In the case of identification of recurring errors or problems, *Kaizen* is employed to remove the repetitive jobs.

- **PokaYoké:** Several processes are automatically controlled with self-checking functions which stop the process if a problem occurs with the help of PokaYoké [345]. These are fail-safe devices that act as safety devices, preventing not only defects from passing through, but injuries as well. For example, for fitting some critical parts, these parts racks are fitted with sensors, and an alarm sounds if the wrong part for that particular engine is selected. Some tightening processes have automatic sensing devices, so that

the engine assembling will only be allowed to progress when the required fixing torque has been applied. These processes are verified each time when the line stops to confirm correct operation, and suitably maintained. Sometimes, if the team member is unable to follow the required operation, then the process is also subject to a manual confirmation and the team leader verifies that operation. Records of all these activities are maintained accordingly in a separate file.

6.3.3.3 Other terms used in TMMF

Following is the list of those terms that are used in this case study.

Kaizen: *Kaizen* is termed as continuous improvement, the constant search for the better way, or never ending job redesign. It has two elements, improvement/change for the better and ongoing/continuity. Jobs are improved via *Kaizen*. People who do their job are given opportunities to redesign the job to increase efficiency. However, standardizing the job is the next step after each *Kaizen*.

QMS documentation: The documented QMS identifies the basic methodology by which the EAS operates. QMS documentation has three levels. The first level includes the organization's quality manual and objective, quality policies are in level two, and the work instructions and detailed processes needed to ensure the effective operation and control of the EAS processes are in level three. At *TMMF* detailed procedures are called "work instructions" which detail the necessary activities to bring a particular process of required quality. These should be established and followed by each working department to ensure the effective planning, operation and control of processes. The structure and relationship among the documentation used in the case organization is shown in *Figure 6-5*.

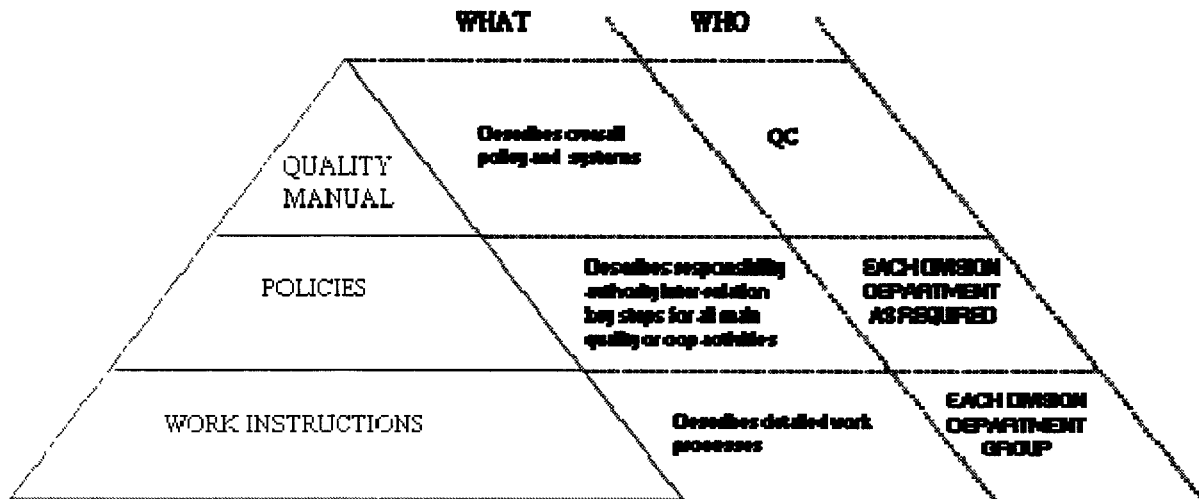


Figure 6-5: Relationship between documents used in case organization

Job Element sheet (JES): JES is the detailed work instruction or standard procedure to do the job. All team members are provided with JES and are asked to carry out all their operations in the order and in the way defined in the JES.

Standard Operating Procedures (SOP): It is a written document that describes in details how a particular procedure or method is executed for repetitive use. It is generally intended to standardize the procedure performance. It is also called work instruction.

Test Table: It is used to train new members and provide basic training for assembly line processes.

Statistical Process Control (SPC) chart: SPC charts are used to monitor, manage, maintain and improve process performance. Data are analyzed to evaluate where improvement can be made by elimination of process deviation. The EAS uses SPC charts to collect and analyze different data processes. All TM are asked to fill the SPC charts and after each shift, the TL verifies the data that are further checked by GL once a week. The objective is to reduce the process variation and use counter measures if any deviation occurs.

5S: It originates from five Japanese words which are as follow.

1. *Seiri:* (Sifting) Differentiate between the necessary and the unnecessary and discard all which is unnecessary.

2. *Seiton*: (Put things in order) Keep things in order so that they are ready for use when required.
3. *Seiketsu*: (Personal Cleanliness) Make it a habit to be clean and tidy.
4. *Seiso*: (Cleanup) Keep the workplace clean.
5. *Shitsuke*: (Discipline) Follow the procedures defined in the organization.

Kamichibai: It is an instruction sheet that refers to the ergonomic movement of body parts while doing an operation on an assembly line. It includes good postures explanations that can facilitate the assembly operation. It is helpful in reducing unnecessary and bad movements of body parts which can increase stress and may result in pain and stress. The sheet is filled once a day by TL to verify that TMs are doing the assembly line operations in an ergonomic manner.

On job training: It is meant to train a new TM on the assembly line. During the training period, a TL assures that the TM is performing in the right way all the desired operations. It continues until the TM is trained enough to perform his job independently.

Post qualification: It means that any TM working on the process is qualified enough to handle and manage the post of a process. A certificate is issued to all authorized persons who are capable of running a process. All TMs and TLs are required to have the post qualification. The certificate is renewed every three months by TLs to ensure that the TM is performing well the key steps of the process and there is no need for any training.

Job rotation: All TMs are encouraged to learn and qualify for many posts of a process or many processes. TMs often change their work post and learn a new process operation. This is called job rotation.

Defect sheet: Whenever, a required task is not correctly completed on the assembly line by TM then the desired operation is done by a TL if possible before the engine passes to the next team. In this case, the TL fills the defect sheet with the nature of operation done and torque values obtained.

Repair activity file: When a defect appears from any engine during assembly, the engine is sent to the repair team to remove the defect. If any operation is left or found during the engine assembly, the engine is sent to the repair team. The repair team notes down all activities done including engine number, defects observed, action done, etc. in the repair activity file.

Test bench: All engines are tested in the test bench to verify their proper functioning.

Calibration: It is a set of operations that compare values taken from a piece of inspection, measuring and test equipment or a gage to a known standard under specified conditions.

Identification and traceability: The *Toyota* vehicles are made with a broad range of specifications and options. Thus, the modifications of design are built-in to continue to satisfy customer requirements. The identification and the traceability of the engine and its components are necessary for several reasons including confirmation of the design level, system requirement, parts deliverance to the right place, correct installation of the parts according to the specifications, traceability in the event of problems and identification of defective material.

Environment Management System EMS (ISO 14001): The EMS demonstrates an organization's ability to anticipate, identify and manage its interactions with the environment, its environmental objectives is to ensure ongoing compliance with applicable legal requirements. It helps organizations to avoid, reduce and control the adverse environmental impacts, achieve compliance with applicable requirements and assist in continually improving environmental performance. Environmental management is an integral part of overall management system. As concern grows for continually improving the environmental quality system, *TMMF* focuses its attention on the environmental impacts of its activities, products and services.

All processes of the engine assembly line were verified through SPC charts in order to observe the process variation. The list of all these processes for SPC charts is presented in appendix 1.3.

6.4 Evaluation of QMS constructs for QM implementation

All processes in engine assembling have a direct effect on quality. So the major objective of the evaluation was to ensure that all processes are carried out under desired standards, identify weaker areas for improvement and meet required conditions of QMS implementation. It involved analysis of the QM practices of the organization focusing on ISO certification for the EAS. The first ISO-certification audit was due in three months and the engine assembly line was facing increased production demand. In order to make the evaluation successful, the work was started by going through the existing quality manual that describes the overall quality policies, the key operating principles, how operations are controlled, responsible teams and members, etc. Secondly, to access the actual condition, an internal audit with “quality and assembly manager” and the “EAS assistant manager” was held.

The evaluation of the organization’s QM implementation practices for ISO certification was done. The assessment was found extremely necessary because if one does not know where one is, one cannot go ahead. Based on the evaluation, the current situations of the organization’s QM implementation and preparation for ISO certification were obtained. *Table 6-1* and *Table 6-2* describe the quality evaluation with observed weaker areas of QM implementation practices for ISO certification. Only weaker areas of the organization’s QM implementation for ISO certification are stressed in the following paragraphs to facilitate the organization in terms of QM implementation. The weaker area term is relative to strong area ones in the organization. Nevertheless, strong areas of organizations are not at all considered in an ideal state and there is always a possibility to improve these stronger areas.



6.4.1 Internal Audits

The internal audits were considered an important step in the process of implementation of QMS and ISO certification. The audit plan was established and communicated to GLs and TLs of the EAS. All major points of QM elements components were identified with the help of an audit to improve weaker areas. It

also includes both the operation and control of processes, availability of resources and supporting information to observe and measure these processes and implement necessary actions for QMS implementation.

A weekly audit was decided later to implement corrective and preventive actions to achieve objectives. The QMS of EAS was assessed with the help of QM implementation and elements presented in this study. However, this was also consistent with the requirements of the organization's quality system principles, as documented and explained by the relevant policies and the requirements of external standards, *i.e.* ISO-9000: 2000.

It was noticed that like many assembly lines, at their initial phases, several quality problems exist, for example: job element sheets were not signed and updated, unidentified material was found at various places, SPC sheets were not properly filled and signed, out dated, including deviation without proper counter measures, calibration stickers missing or unreadable, several workers working at their posts without knowing whether they were trained /qualified or not for that post, documentation not controlled, etc. Following is the list of non conformities of the first audit of the “Blue” team.

Observations	Process	N/C Type	Action plan	Who - Responsible
JES are not signed for all processes of Pre 1	Pre 1	Minor	Verify and sign the JES	TL Pre 1
Repair activities file are not updated	Repair	Major	Update the repair activities and regular follow up	TM Repair
Skill matrix chart is not updated	EA	Minor	Update the skill matrix chart to know the trained team members	GL Blue

Table of TL contains several unidentified equipment (oil pump and oil strainer)	Main 2	Major	Identify all defective items and remove all unidentified material	TL Main 2
File of Kamishibai has not been filled in for the last month	Final	Minor	Start filling the file and regular follow up is required	TL Final
SPC control sheet # 50/57 – K420 “Intake Manifold” torque very high: 2 N.m. No graphical representation, no countermeasures and actions mentioned.	Final	Major	All torques should be noted and in case of variation, a counter action is required. Inform TL, GL to take necessary measures	TL Final
JES are not signed for process 19 Main 2	Main 2	Minor	Verify and sign the JES	TL Main 2 TM Process 19
Team member is trained for processes of Pre 2. He is working at P3. Skill matrix chart does not match the training.	Pre 3	Major	Training for the Pre 3 is required and update the skill matrix along with post training file.	TL Pre 3
Quality policy is not known to TMs	EAS	Minor	Communicate the quality policy to all TMs	AM
On job training file of TMs is not signed by TL	Process 20	Minor	Validate the on job training file and follow up	TL Main 2

SPC control sheet # 43/57 – K310 “Water pump pulley” torque mentioned is not readable and no graph is sketched.	Main 2	Remark	All torques must be clearly noted with appropriate graphical representation	TL Main 2 TM Process 21
SPC control sheet # 41/57 – K375 “Clutch cover” torque mentioned is high	Main 2	Minor	Take counter measures to remove upper variations	TL Main 2
Shelf of flywheel reduces the passage for next process	Process 18	Remark	Security risk : all processes should have at least space of 80 cm	AM
Calibration sticker is not readable on the torque wrench # 3171660	Process 19	Minor	Send the torque wrench to calibration laboratory and get the readable sticker	TL Main 2
SPC control sheet # 34/57 – K350 “Oil pan assembly” at process dated 2 months old and is not completed	Main 2	Major	Fill the SPC sheet and regular follow-up is required	TL Main 2
Balance is not calibrated	M1S07	Minor	Send the balance for calibration and paste certificate sticker	TL Main 1
No SPC sheet is signed and checked by TL and /GL. No cross check and counter measures in case of variation	Pre 2	Major	Define a clear policy about the utilization of SPC sheets and its verification	AM

SPC control sheet # 201 – K455 “Thermostat bracket” torque is very low 8N.m	Process 10	Major	All torques with variation must be checked through clear actions to remove the process variation	TL Pre 3
Kamishibai file has not been filled in for the last month	Pre 1	Minor	Start filling the file and regular follow up is required	TL Pre 1
Audit of post qualification verification** of TM has not been done for the last three months	Process 7	Major	On job qualification and training of all TMs must be done according to the organization policy	TL Pre 2
No calibration sticker was found on the torque wrench # 3171666	Process Main 1	Major	Send the torque wrench for calibration	TL Main 1
A TM is not trained for the process because he is on an interim basis	P10	Major	All TMs working on the assembly line need to be trained and must have the training record	TL Pre 3

Table 6-1: List of Internal audit of team A including non conformities

** An audit of post qualification verification of all TM was required every three months from their TL in order to validate their expertise. This verification allows the TL to know the level of expertise achieved and required from a TM for a specific process.

The same audit was also conducted for the “Yellow” team. Below are the findings of the internal audit:

Observations	Process	N/C Type	Action plan	Who - Responsible
Skill matrix chart is not updated*	EA	Minor	Update the skill matrix chart to identify the trained team members	GL Yellow
Test Table of EAS is full of unidentified materiel (oil pressure switch, oil relief valve, head bolts, water temperature sensor assembly and oil drain plug)	EA	Major	Identify all defective items and remove all unidentified materiel	GL Yellow
SPC control sheet # 24/57 – K295) “Chain cover bolt” torque very high: 15 N.m. No countermeasures taken and actions mentioned.	Main 1	Minor	All torques should be noted and in case of variation, necessary countermeasures are required to remove process variation. Inform TL, GL for further actions.	TL Main 1
Bolt box is overfilled	Main 2	Remark	Risk of fallen bolts	TL Main 2
A TM is working on Process 17 and he is not trained for the process	Process 18	Major	Training is required to do the operation and mention it in the on job qualification file	TL Main 2

JES are not signed for all processes of Main 1	Main 1	Minor	Verify and sign the JES	TL Main 1
Calibration sticker are damaged and not readable on the torque wrench # 3171685	Pre 2	Minor	Send the torque wrench to calibration lab and get the readable sticker	TL Pre 2
SPC control sheet # 34/57 – K350 “Throttle stay” tolerance (21+-4N.m) does not match with the QCS chart (24+-6N.m)	Main 2	Major	Correct the SPC sheet according to QCS	TL Main 2
Balance is not calibrated	M1S07	Minor	Send the balance for calibration and display certificate sticker	TL Main 1
No SPC sheet is signed and checked by TL and /GL. No cross check and counter measures in case of variation	Pre 2	Major	Define a clear policy about the utilization of SPC sheets and its verification.	AM
Flow rack contains several crankshafts without any plastic protection	Pre 2	Minor	Absence of protection can cause dirt on the crankshaft and all sensible items should be uncovered only at the time of assembling	TL Pre 2
Overflow of crankshafts on the flow rack	Pre 2	Minor	Flow rack filling of crankshaft should not exceed shoulder height.	TL Pre 2

			Risk to damage crankcase in case of fallen to ground	
SPC control sheets # 23/57 – K295 “Timing chain cover” torque measured is very high 12N.m not verified by TL and GL	Process 14	Minor	All variations must be controlled through proper counter measures to assure the process stability	TL Main 1, GL
SPC control sheet # 201 – K455 “Thermostat bracket” torque is very low 8N.m	Process 10	Major	All torques with variation must be checked through clear actions to remove the process variation	TL Pre 3
Kamishibai file has not been filled for the last two months	Pre 1	Minor	Start filling the file and regular follow up is required	TL Pre 1
Audit of post verification knowledge of a TM is has not been done for the last three months	Process 11	Major	On job qualification and training of all TMs must be done according to the organization’s policy	TL Pre 3
No calibration sticker was found on the torque wrench # 3171669	Process Main 2	Major	Send the torque wrench for calibration	TL Main 2
A TM is not aware of tolerance limits of the process P2 Final 2	Final	Minor	Training is required to understand the tolerance limits of the process	TL Final

Over flow of piston on the flow rack (kanban 2337)	Pre 2	Major	Problem of overflow, box of 32 or 48 pistons maximum should be placed.	TL Pre 2
Oil of different types was found without proper identification	EA	Minor	Identify all types of oil	TM Repair
TM does not know the basic conditions of tightening. <i>i.e.</i> Poke Yoke, SPC sheet and visual control	P13	Major	Training is required for TMs to know the tightening rules	TL Main 1
JES is not available	P 10	Major	Prepare the JES and make it available	TL Pre 3
A TM validates his Poke Yoke before taking the assembling piece	P10	Minor	Respect of process is required which is first to pick the assembling part and then validate the Poke Yoke	TL Pre 3
A TM does not respect the sequence of the process and inverses several sequences of the process	P10	Major	Apply the defined standard or modify the tightening sequence accordingly	TL Pre 3
Defects sheet has not been filled in for the last 3 weeks	P18	Minor	Use the sheets in order to trace the defects	TL Main 2

A torque wrench was found non calibrated and non identified	EA	Major	Send the torque wrench for calibration	GL

Table 6-2: Internal audit of team B including non conformities

* The organization asked to update the skill matrix chart every three months in order to know how many members were trained and on how many posts.

6.4.2 Evaluation of quality elements

This subsection presents the weaker areas of the organization's QM implementation and the reasons leading to these weaker areas. The weaker areas identified could be used by the organization to further improve its QM implementation; they were regarded as potential improvement possibilities. Note that the identification of these weaker areas was on the basis of fact-based audits. These audits were to make sure that a documented system meets the standards adopted by the organization. All non conformities identified lapses in the implementation of the system and were classified as minor or major non conformities based on their impact on the system.

6.4.3 Top management

It was observed that JES were not signed for the processes of the EAS. Top management was responsible for ensuring that all the necessary work instructions and documented procedures addressing all critical issues were planned, verified and applied. Work post audit verification was not done regularly. Skill matrix charts were not updated according to people skills and competency that demonstrated that QM was developed but not used on regular basis. Everyday use of all quality documents is important to improve the implementation of a QMS. Without daily usage, QMS exists but is not implemented. SPC charts were found incomplete which demonstrated that the role of top management was not fully played to make people aware of quality tools importance. Top management is not meant to provide only quality tools but to strongly encourage people to actively use those quality tools for process management. It indicated that the QM was not

in regular use and thus little possibility of change for the quest of improvement was visible. The organization was focusing towards its business but less importance was given to the EAS. There was a low tendency for employees to act according to what the QMS procedures asked to maintain the quality system. Employees did not use quality tools (SPC charts, calibration, etc) properly as most of them were not aware of their importance, proper use and advantage. Top management did not pursue on process management, training and utilization of quality tools but focused instead on increased production, which was their more important goal. Top management gave less importance to all the above elements than they deserve. Top management was committed to quality by introducing quality tools like SPC but a regular follow up and proper training to make the employees familiar with them is of great importance. In addition, top managers are responsible for goal setting and for creating and sustaining change as needed to remove all existing deficiencies and non conformities and for a regular follow up. After our audit, managers organized meetings for the EAS in order to know the current situation and how QM system is being implemented. We observed that quality integration of QM system was not given sufficient attention. Quality integration in the EAS was not fully adapted and assimilated, and as a result, QM standards were not fully planned for “everyday use” which is to adapt it in daily routine and thinking as a catalyst for change for continuous improvement. Employees were reluctant to use the QMS in daily practice and implement it as a catalyst for change. They did not have the same perception about the QMS as compared to the top management about the tool utilization. Employees were not taking full advantage of the QM implementation and top management was responsible for less involvement of employees in the QMS. Thus, it can be stated: *Less the QMS is accompanied by top management, less the problem of the QM implementation is solved.*

6.4.4 Strategic quality planning

The organization worked to develop a long-term strategic quality planning before installing this plant in France. However, many employees were not approached to describe the organization planning or even the EAS quality planning and policy. Quality policy was important to communicate so that employees of EAS made decisions that were consistent with and supportive of the strategic

quality planning. The communication-to-inform process seems important to assist employees to apply organization's policies. Due to an unawareness of quality planning, many employees were not at all clear about the organization's strategy. In fact, the organization did not use it as a guide in formulating its business strategies. In this regard, the management of the EAS did not communicate the organization's strategic planning to the floor members. One of the major reasons was the workload on Manager in terms of operational activities (responsible for production lines). He was handling a number of employees in addition to the EAS including paint, body shop and press. He did not find time to schedule and communicate the strategy with his Assistant Manager of EAS. Moreover, the management focused on operation performance and worked on a target to accomplish full production rather than to promote the organization's strategies and policies to all employees. Usually the major objective of strategic quality planning is to know where an organization will be in the coming years, and the path that follows for future achievement. It reflects the willingness of an organization to demonstrate its capability to achieve its target and its working attitude. However, when asked from a TM of the EAS about the quality policy of his department. He was unable to reply because he was not aware of it. The same reply was given by another TM of another team too. This indicates that the quality policy of the EAS was not well communicated to all EAS employees. This lack of awareness created a gap among management and employees that in turn affected the way the business was getting done. When management places much emphasis on operations without sharing the strategic quality planning, people do routine jobs without being involved. The information used in making strategic planning is short lived if the element of integrity in all relations is absent. Thus, management should pay strong attention to communication-to-inform process that informs and accepts to exercise the responsibilities and authority following the organization's strategic quality planning. It was advised to promote the organization's strategic planning with the help of published instructions, A5 size plastic coated copy of quality policy for each employee and training material that was intended as an aid in connection with the implementation of the organization's standards. Thus it can be stated: ***Less the QMS is accompanied by strategic quality policy, less the problem of the QM implementation is solved.***

6.4.5 Employee's training

The organization did not continue pursuing the necessary quality training to its employees to carry out their activities with excellence, and a constant support in terms of awareness for QM implementation was found missing. The organization used SPC charts to monitor the process deviation. However, no appropriate training was provided to employees who were responsible for using these charts. They did not use this chart even in daily routines and considered it as a burden. According to some employees, the SPC charts were of no use and it was an additional burden to keep the workers busy. An excellent quality tool was called to question in the assembly line because of a weak culture of quality awareness and training. The organization did not implement the training plan according to the strategy and current employees' skills and their requirements. All EAS members had an important role to play in the engine assembling, and had direct influence on the quality of the product-engine plays the central role in a vehicle. Constant focus on training combined with experience allows employees to look for better ways to carry out their responsibilities. Without proper training, an organization cannot achieve its objectives. In training, the team members were given the opportunity to explore and enhance skills and abilities to cope with the quality problems found during our assessment. In addition, we found deviation in process management in terms of documentation verification by TMs who demonstrated that if they were trained enough on SPC and quality issues, most of the observed problems could be better handled. Training help improve employee skills and as a result improve processes.

The organization did not fully implement the system of job rotation as some of its employees were hired on an interim basis and some training was not properly documented and mentioned in the job rotation file. As a result, the job rotation file and work post qualification files did not translate the real need of training. For example, we noticed a team member without a qualification certification working on a process and due to the nature of his (temporary) contract, the company did not provide him with full training and a certification. In general, nobody should be allowed to work unless he is authorized to work on his specific process. Therefore, employees lacked multi-disciplinary skills.

The organization had adopted the rule of overtime payment that were attractive and were conform to the industrial norms applicable in France. However, the employees did not appreciate overtime especially on Friday. During my work period, it was observed that people were not constantly explained the reasons behind the regular overtime. The major reasons include higher demand in production and the organization's policy of zero stock. The organization must inform on a regular basis the reasons behind any such move on regular basis.

Two team leaders were found reluctant to share their ideas, knowledge and even training material they possessed which they got in past training. There was a tendency for those team members to hold their skills to remain competitive among all team members. For this reason, the skill and knowledge those members possessed were not widely shared to other teams. Top management attempted to provide training programs in the past by introducing quality training; however, this practice was limited and insufficient as compared to the increased production and establishment of new production lines. Acquisition of specific skills and knowledge of all relevant information plays an important role in running the process. Thus it can be stated: *Less the QMS is accompanied by employee's training and learning, less the problem of the QM implementation is solved.*

6.4.6 Customer Focus

This issue was beyond the scope of the study and I was not involved in studying the customer focus. However, I focused on the concept of "next process is the customer" which is already integrated in the organization's production system. Usually, all engines were tested on the test bench in order to verify the engine's performance. I insisted that the test bench is the "next customer" and the EAS received feedback on engine assembling once they were delivered to the test bench (customer). The feedback was then processed with more care, and passed on to the relevant areas of the EAS, so that any necessary corrective or preventive action could be taken. This concept was helpful for employees in better understanding customer requirements as inputs. Monitoring of customer requirements until satisfaction requires the evaluation of information whether the process has met those requirements. This depends on constant communication to meet the requirement. This entire concept ensures the final product. The test bench

team leader informed us in a meeting that his team was able to better understand the working approach of the EAS because of constant communication and necessary actions from the EAS to avoid problems on the test bench. Though, the following element was not treated in terms of an external customer. However, in the case of next process is the customer, it can be stated: *Less the QMS is accompanied by customer focus, less the problem of the QM implementation is solved.*

6.4.7 Process Management

A moving engine is a very significant source of vibrations over a long duration. It is thus essential that the prescribed tightening torques be respected. The tightening torques of engines were calculated according to materials of the part and the screw (surface quality and coefficient of friction). These SPC charts determine the appropriate range of tightening nuts and bolts, sequence of operation and tightening range, verification of different parts in case of multiple engine models. These charts are considered an important part of monitoring, managing, maintaining and improving the course performance.

The quality engineer told me that soon after the start of the engine assembly line in April 2002, it was noticed that the tightening torques of many nuts, bolts varied much and fell outside of accepted tolerance. The quality control department then deployed the SPC charts to monitor process stability and communicated the results to the EAS when required. However, the team members were neither well aware of the utilization of SPC charts nor the reasons to using these charts. At the time of audit, it was observed that some SPC sheets were not filled by the workers for several reasons (lack of time, difficulty in completing the process, ignoring the instructions, feelings that SPC is a waste of time). Our assessment further revealed that the organization did not focus on the real use of tools and techniques for the quality improvements through SPC charts. In the course assessment, I observed that various processes were in the range of deviation with no corrective and preventive actions in place. Many SPC charts were not properly filled-in, missing numerous values, including no graphs and no verification from the respective managers.

Then, the quality assurance engineer, who worked on the preparation of SPC sheets for the QA department, and I worked to familiarize team members with SPC charts for the engine assembly line to monitor the process. It was an opportunity for the team members to view the process and involve themselves to be aware of the approach. We worked on two axes including explanation of SPC charts and elimination of variation in the of assembly line process. We first identified the areas where the process deviation existed and then discussed with respective team leaders to identify the possible causes. With three months regular feedback, 80 % of deviation were reduced and were brought into the tolerance range.

The organization calculated its process capability index in order to understand whether the process was stable or not. However, the effectiveness remained limited because the utility and exploitation of information through the quality tools were not well explained to the employees. Thus, management was not implementing a successful process management approach through SPC due to the lack of understanding of the techniques and its capability within the organization. SPC charts were meant for many employees to collect data only. However, analysis to demonstrate the suitability and effectiveness of the QMS employed in the EAS and to evaluate where improvement can be made was not considered by most of the team members. Team members did not follow SPC charts. As a result, monitoring and measurement of these charts were not found helpful to provide related information about the process and product trends including opportunities for preventive action. Thus it can be stated: *Less the QMS is accompanied by process management, less the problem of the QM implementation is solved.*

6.4.8 Communication-to-inform process

The organization did not fully utilize the communication-to-inform process that is essential for a good cohesion between teams to carry out the required tasks. The quality department introduced SPC charts to monitor the process stability in the EAS. However, little efforts were done to explain these charts to all employees who were using these charts. People were not aware of its utilization and how to take advantage of this tool. Effective communication was lacking which in turn limited the importance of SPC charts. The quality department and the EAS

required a constant interaction to achieve quality goals. It was found that many lapses existed among quality practices implementation especially in documented QMS. Information provided in the JES was not implemented in the daily processes. There was a gap between QM documentation and QM implementation practices. I discussed with all TM about their JES. Through communication, we were able to remove the incoherence between actual and mentioned practices. All TM were invited to discuss and improve the JES before final validation. All documents that were not updated on a regular basis were the source of mis-information for auditors. Communication-to-inform process is key factor for the achievement and the follow-up of quality objectives as well as for control activities. There is a need to avoid or reduce the barriers that can lead to unsuccessful communications. In this case study, I tried to reduce the lack of knowledge of EAS members about QM with the help of a communication-to-inform process. Team members' views were taken into account after each training session to know how they perceived the training provided. QM terminology was developed before training sessions and I used frequently these words and terms while discussing with team members in the way they use these words. In discussions with TMs I attempted to provide a means to exchange and share information and ideas. These discussions took a great deal of time and efforts to remain productive for QMI. I tried to benefit from the communication-to-inform process to ensure that TMs were working cohesively on the implementation of QM. They are also monitoring tools. The main information and communication activities between departments were anticipated again after internal audits. Active participation from top management to guarantee that internal control and monitoring requirements were taken into account was considered to be important. The major reason for not fully deploying the quality tools was lack of information and communication. Thus implementation of several training sessions was done to communicate the importance, usage, evaluation of information attained through regular training programs within the EAS for all employees. Database for engine repair activities and daily repair activities were created to gather information related process management. Analysis and communication of all the relevant information in an effective way is helpful for all employees to plan, prepare, and to participate in quality matters. Without communication the establishment of good working relation to ensure the QMS, is not possible. I organized the SPC and

quality audits session with all TMs on an individual basis before organizing a combined training session for all employees. The reason to hold individual session was to make people comfortable about these issues and to know what they think about these subjects. This phase was found very effective as people had not heard about these issues before. Team members were not aware of the ISO certification process. They considered it as an inspection to find defects and defaults in order to give a penalty to the concerned people. So It was better to stay away from the auditors whenever possible to avoid any possible consequences. These ideas and information spread inside the EAS. After giving 5 to 10 minutes to each member to express their perception of ISO, I clarified their misconception about the ISO certification. For SPC, some asked the reason why we were using these SPC charts. Some team members considered SPC as the inspection of their personal work by quality department. That is why, numerous SPC charts were found not properly filled-in. All their remarks were considered and the SPC charts were explained. The communication and sharing of information about QM paved the way to improve management control process. People then communicated easily about the SPC problems whenever they found in the process on daily basis without hesitation after these training and discussion sessions.

It was found that the creation of process management for two-way communications to facilitate the sharing of vital information, issues, and ideas among all the EAS employees was vital. The organization did not ensure that their employees were well informed about critical issues concerning the organization, including their strategy, process management challenges and training. A quality manager was also asked to speak about QM implementation that helps employees do their job more effectively and play their roles in achieving the organization's goals. Thus it can be stated: ***Less the QMS is accompanied by communication-to-inform process, less the problem of the QM implementation is solved.***

Thus if we summarize the above quality elements, it can be stated:

Less the QMS is accompanied by **quality elements**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **top management**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **strategic quality policy**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **personnel training**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **process management**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **customer focus**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **communication-to-inform process**, less the problem of the QM implementation is solved.

6.5 Evaluation of QMS implementation phases

In fact, this implementation reflected the level of the organization's QM. The assessment of the organization's implementation phases could be used as input for formulating an effective improvement plan. Therefore, evaluating implementation phases was also an important part of a complete QM implementation.

6.5.1 Quality integration phase

The organization did not fully recognize the quality integration phase. Quality integration is assimilation towards QM to work which conforms to QM based on the organization's formalized procedures. Thus, it commences with the

commitment of top management as a first step in order to help people to integrate, coordinate and adapt this phase. When the case organization decided to lead towards ISO certification, the organization worked to accommodate the new applicable rules with its existing ways of doing business. The case study organization has strongly proven best practices adapted to meet business requirements. However, all the people did not have the same vision about ISO standards nor were they involved to work accordingly. A documented QMS was developed covering all necessary procedures to conform to the ISO standard. But, common vocabulary for ISO standards was not used to understand this applicable system in the same way for all departments as compared to the quality department. Utilization of procedures and their application in everyday use was not found consistent everywhere in the EAS. Employees training procedures to maintain the new standards were not fully applied. Explanation of the process management remained unclear to a certain extent. Many team members were asked about the quality integration phases of ISO 9001 standard implementation in the organization. I presented these audits and discussions with facets that might affect the quality integration phase. Many standards were not followed in the way they should (documented quality procedures) be approved to support the QM implementation. It was difficult for the organization to improve the implementation level of QMS in this way.

Employees' quality integration was found to be low due to the lack of a common quality vocabulary and quality language. That is why employees still lacked a strong sense of responsibility to implement QMS in the viewing and operating processes. Fewer occasions of constant dialogue among quality department and the EAS were observed. In addition, a number of employees were short of sufficient skills needed to perform their jobs well. Some production equipment was not calibrated and could harm the desired quality level. The organization did several innovations in the production line to pursue long-term business success, however, the consistency to use everything was not fully found by employees. Top management was required to do more for employees to achieve goals of the organization in terms of training, communication and quality information sharing.

The organization conducted regular measure using various product quality indices, such as number of defects for the assembled engines, etc. and the parameters of performance, reliability, and durability were specified. Before finished products were delivered, their performance had to be examined; otherwise, they could not be delivered to customers. If finished products met the requirements of their technical specifications and performance indices, then the conformity rate for these products was 100%. Generally, the indices of reliability and durability could not be checked in advance but could be examined through practical application of products on site. The number of defects for assembling engine parts was measured in terms of defective pieces, the assembly line where the process was held defective, number of recurrence and its impact on EAS. Actually, the organization was one of the best in the automobile industry in the world. Its product quality enjoyed a high reputation throughout the world [217] indicating that the organization's product quality was superior.

The management of the EAS accepted our action plans to improve the quality integration phase including improved communication among top management, quality department and the EAS towards QM issues, use of common quality vocabulary, sharing of quality information about job environment and QM impact. Thus, it can be stated: *Less the QMS quality integration phase is accompanied by a QM standard, less the problem of the QM implementation is solved.*

6.5.2 Quality daily use phase

Some documented procedures were not regularly used in daily routine activities. For this reason, their effects on the organization's QM and its product were minimal. The organization conducted a training session mainly through the quality department on SPC and JES. The knowledge achieved from these sessions was limited and the number of employees increased due to the increased production demand. New employees did not receive constant and thorough training that were the major sources for the process management and in understanding quality tools and doing the job in a more effective way in routine jobs. Those employees who did not have the same perception about JES, SPC, etc were not

involved in deploying these quality tools in their daily activities. Tools were found not calibrated and unidentified material was placed at unauthorized places though all procedures existed in the QM documented system. Development of a documented system remains an important condition for QMS, however, without daily practice, it cannot be regularly applied as a standard. Daily use is the point when a practice becomes a part of an organization's everyday routines. At this stage, no one is required to prepare for audits at the last moment because there is no gap in the organization's procedure and its implementation.

Through conducting the assessment of QM implementation, the organization's everyday quality use phase was identified as weaker than compared to the existing quality tools. The SPC charts information could be used in formulating an improvement plan to improve process management and as a result the EAS processes. Test bench complaints about engine testing could then be reduced. The major reasons leading to low level of quality in everyday use were recognized as: lack of awareness in using the quality tools and less support from top management to integrate employees with QMS in place that extends the irregular use of the existing quality practices on an everyday basis. As a result, fewer efforts were presented from employees to systematically enhance the QM implementation. Despite the deployment of Kaizen (continuous improvements) concept in the organization, change factors to motivate employees for improving the system was not very effective. Without successful implementation of this phase, identification of improvements in the system remains static, limited and occasional. Thus, it can be stated: *Less the QMS quality of the everyday use phase is accompanied by a QM standard, less the problem of the QM implementation is solved.*

6.5.3 Quality system evaluation phase

The organization regularly measured its annual sales, sales growth, profits, market share, and exports. These indicators were a great source for the organization to work on improvement as being a world class organization, all the above factors were constantly increasing and paved the way to improve the quality of products and QM implementation. Among others, ISO certification for

organization was sought as the way that could be used by the organization to develop and implement appropriate actions in order to improve its QMS. The reason behind the project, led by me, was part of an evaluation of the existing QM practices to measure the satisfaction level of the QMS organization. The organization was found willing to measure the difference between the actual performance and the desired goal to improve the existing system. Evaluation was done with the help of internal quality audits for quality elements and QMS implementation to measure the room for quality improvement. Certain weaker areas were identified to improve the way things were being done. The weaker areas identified during evaluation helped the organization's QMS conformance to written QMS but also improve the organizational performance. Thus it can be stated: *Less the QMS evaluation phase is accompanied by a QM standard, less the problem of the QM implementation is solved.*

If we summarize the above quality phases, it can be stated:

Less the phases of **QMS implementation** accompanies a QM standard, less the problem of the QM implementation is solved.

Less the **QMS quality integration phase** accompanies a QM standard, less the problem of the QM implementation is solved.

Less the **QMS quality daily use phase** accompanies a QM standard, less the problem of the QM implementation is solved.

Less the **QMS evaluation phase** accompanies a QM standard, less the problem of the QM implementation is solved.

6.6 Improvement plan of key elements

Identification of several weaker areas was done to prepare improvement plans for the system. The key elements involved include assessment and verification of:

- Quality policy awareness

- QM Documentation
 - JES (Job Element Sheets)
 - Work-post training qualification and skill management charts
 - SOP for the EAS
- SPC charts to monitor process activities
- Identification and traceability of material (wastes, defects, repairs)
- Calibration of testing equipments
- Several training sessions included material (definition, reasons to use, how, why and where) for individual and team basis including:
 - SPC
 - 5S
 - QMS and ISO audit certification preparation
 - EMS (Environmental management system)
- Database creation to monitor engine repair activities

6.6.1 Quality policy awareness

Regarding the quality policy developed by the top management, it was advised to be communicated in all areas. All team members were given briefing about the organization's policy for the EAS. It seemed helpful in the deployment of policies and objectives achievement.

6.6.2 QMS documentation

As discussed in chapter four, ISO requires documented procedures for QM are documentation control and proper records, audit, control of nonconforming

products, corrective and preventive actions to satisfy customers. According to the audits finding for the weaker areas, documentation including JES, work post qualification, skill matrix and SOP were examined. It was ensured that all established documented procedures were reviewed, updated, approved prior to issue, and that relevant versions of applicable documents were available and their distribution was controlled.

6.6.2.1 Job element sheets (JES)

All TMs were provided the opportunity through group discussion to give them well defined roles to perform their responsibilities in the required way. All employees were expected to contribute in defining their due role described in JES with their TLs, coordinate with other employees and teams to fulfill the common organizational objectives. For this purpose JES were reviewed and discussed in detail, with TMs and TLs, which was the exact explanation of what is being done on the assembly line, to assure their responsibilities in the process. Distribution and control of these documents were done to ensure that the team members received the latest versions, and all invalid or obsolete documents were destroyed. Modified documents were given the revision level with an issued date. An electronic version of all these documents was provided to the quality department in order to update these documents according to the nature of the change. All documents were reviewed and approved by concerning Manager and Coordinator of the EAS.

6.6.2.2 Work post qualification and skill matrix chart management

Work post qualification for all the EAS members were verified and updated accordingly. On the job training was verified to ensure that all workers were trained well enough to perform their job on the assembly line. Each GL validated the effectiveness of this documentation. Training records were maintained showing authorized members how to operate or adjust equipment or processes. The skill matrix charts were updated in order to take a real picture of skill management. Multi-post training and skills were developed on the assembly line to increase the autonomy of team members working on different processes. The competency matrix charts of yellow and blue teams working on the EAS are presented in appendix 1.4.

6.6.2.3 SOPs for EAS

The management of the EAS was told to update all procedures. All SOPs were verified with the help of the quality department according to the actual EAS usage. These documents were then approved by the Manager and Japanese coordinator. The quality department and I elaborated several procedures including:

- Management of Work Instructions for EAS
- Tools Management at EAS
- Waste Management
- Management of engineering changes instruction
- Operating principles of the repair platform
- Principle of tool utilization and control
- Principle of utilization and control of Pokayoke
- Training and work post authorization of the engine assembly members
- 5S Audit
- Process Control in engine assembly
- Document archiving of engine assembly
- Environment management of engine assembly
- Rules of sorting of waste of engine assembly

The last two SOPs were related to environment management system (EMS) which is required for ISO: 14001 certification. After the successful implementation of QMS, quality and assembly manager were asked to finalize those SOP with the help of the EMS team.

6.6.3 SPC charts

As discussed in the previous section, I worked with the quality department to deploy SPC charts as a tool for confirming product and process capability. EAS verified process variation and torque values with a sampled check of every 50 engines to confirm the continuing quality of the process. It was observed that tightening torques values were a source of significant variation in the process. The quality department engineer and I worked to identify the processes responsible for this variation and to prepare and implement necessary actions. The work involves the assessment of the SPC charts results to discover the source of variations and involvement of team members to participate to better manage and implement SPC charts. SPC is extremely important when inspection of all parts is expensive, unreliable and provides little information. Thus, training on SPC charts for all employees was also conducted. After the training session, team members started using the SPC charts with all the required information including engine number and observed torque values. In order to have a look at the difference of the teams' behavior before and after the training and utilization sessions of SPC charts in the EAS is presented in *Figure 6-6*.

197

198

Figure 6-6 is the SPC sheet of the team “A” working with their old style by ignoring the quality values of the assembly line and *Figure 6-7* is the SPC sheet of the team B working on the same assembly line resulted in excellent work after awareness sessions were provided. From both figures, it can be concluded that the standardized results of team “B” were improved, in respecting the SOPs, whereas the results of SPC of team A lacked various important data. The list of charts used to measure the torques used with the help of SPC charts is presented in appendix 1.4.

6.6.4 Identification and traceability

It was strictly advised to remove all defective or under-repaired material from the normal storage or handling location to specially designated areas with clear identification tags. Team leaders assured that no defective parts were mixed with other material. Defective items were clearly identified, and once the extent was known, a judgment was made to repair on or off line, or in extreme cases, scrap the product. Depending on the type of problem, a record of each defective piece was kept.

6.6.5 Calibration

Calibration of all test equipments guarantees that its capabilities meet the requirements of the task. We ensured that all testing equipment is suitably calibrated and maintained. These pieces of equipment were verified and we sorted out several actions to ensure their proper functioning:

- All equipment was recorded in a file with information marked on the tag with the next due calibration date to track calibration status.
- All equipment was verified against their calibration tag. All unreadable or without tag equipment were considered non-calibrated and were sent back to the calibration laboratory for calibration.
- Records of equipment were maintained by each team and updated.



6.6.6 Training

Several types of training sessions were conducted. It included work post qualification, SPC, 5S, QMS, ISO audit preparation, and EMS awareness.

The key element in these training sessions of every member was to familiarize him with the standard method for performing the job to the required quality.

6.6.6.1 Work post training

As discussed earlier, engine assembling is the heart of the vehicle and all teams working on the assembly line are linked with product quality. It was ensured that appropriate training was provided to comply with applicable requirements to which the organization subscribes, and to achieve QMS objectives on an ongoing basis. Two mock-up samples of processes were provided on site to train workers on the assembling process before they join the production line. Three steps were involved including the following:

- Verification of training held in the past for a work post;
- Identification of employees lacking training on multiple posts;
- Provision of training for those employees.

After these training sessions, GLs ensured that everyone was aware of more than one process and could contribute to another post in case of need. GLs maintained all appropriate training records, and training and skills matrix chart of the EAS.

6.6.6.2 SPC Training

Training on SPC was to ensure that the statistical process control techniques were used correctly by team members. We explained to all workers that the lack of data in SPC charts can affect the process capability and product performance. We informed all workers through simple examples that SPC related

records were not only data entry but were an internal operational requirement to provide evidence of quality control, standards and historical data.

Each team member was given training to fill the SPC chart properly, to identify the system deviation if it occurred, which requires control and precautionary steps to follow and which it has primary responsibility for, and inform the team leader in the case of deviation approaches towards its limit. We focused on the importance of maintaining the system in the stable state. We equally advised them to maintain and to register all the records with engine numbers and torque values. Documented summaries of the identified deviation were asked from their team leaders and group leaders as required. We made it clear that it is the responsibility of the team of each process in which these records were being registered to ensure that the records were entered in a detailed manner to prevent damage, absence of data and can be retrieved as required. The quality department and I informed the workers that records of these inspections should be maintained as these records would confirm that the required inspection and testing was carried out during its assembling and the engine is completely reliable.

6.6.6.3 Trainings on 5S

The 5-S programme that originated from the five Japanese words (1.*Seiri* - sifting; 2.*Seiton* - put things in order; 3.*Seiketsu* - personal cleanliness; 4.*Seiso* - cleanup and 5.*Shitsuke* - discipline) is of great importance in the organization. Identification of several non conformities during internal audits focused on several 5-S audits for the processes. The basic definition of 5S is presented in section 6.3.3.

During the 5-S training, top management played an important role to encourage its team members. The day after the second 5-S training session, it was observed that workers were tired enough after a long shift with overtime and their last task, which was to pick the nuts and bolts, was advancing slowly. The assembly line coordinator (director) helped them to remove these nuts and bolts and motivated the whole team in an instant. Everyone took it as a very cooperative step. It was proved that top management commitment is the most important step for any standard implementation.

6.6.6.4 Trainings on QM and audit preparation

For the purpose of putting in a place a culture of quality awareness of QM implementation, all team members were provided with training, which covered the basic quality definitions employed in the organization. ISO audit preparation, QM explanation were also the part of our training sessions. All training sessions were done twice, individual and group basis.

Periodic training on ISO was provided and I conducted the first session. The purpose of this training was to deliver the basic notions of quality and ISO certification.

- The quality and assembly manager provided two lectures of his experience and expertise on QMS and ISO to all the EAS employees.
- Safety trainings and ergonomic usage of posture and tools were also conducted again to recall and train workers about the right way to carry out the works in a safe, ergonomic manner and to observe basic safety rules on the site.

The training on the quality system and ISO 9001 certification included the following elements:

- What is ISO 9001 and what is the objective of quality audit? And what will be checked by the auditors?
- What can the auditor ask?
- The 5-S: to work by maintaining cleanliness.
- The respect of the standards: QCS and JES
- A complete check of the engine after every 50 engines with the help of SPC chart.
- Training and post qualification of the team members.
- Use of the calibrated instruments.

- Identification of the rejected and defected material by tags.
- SPC chart explanation.

Trainings concerning ISO, SPC, quality and audit preparation were of great importance to reduce repair activities for the production line. To complete these tasks successfully, quality awareness proved as a key element to attain best results that require efforts from everybody. Quality definitions were explained to all workers to promote a quality culture. As a result, an internal audit sheet was developed that was used by TLs and GLs to conduct internal audits. The table is mentioned in *Table 6-8*.

Line:	Process:		
Auditor:	Date:		
JES Management		Yes	No
	The JES file is available at work post		
	The file is complete		
	Assembling sequence + operation cycle time		
	5 principles of good assembling		
	Quality key points (compulsory for security, confusing rack - similar piece or interchange nut, bolt, etc..., backup procedures)		
	All JES are signed by specialists & 2 G/L		
Tool Management			
	The tools that are not used are identified as non-conformed		
	All tools are protected by anti-scratch		
	Material recommendation receipt is archived and signed		
	SPC charts are signed and updated		

	Tool calibration date is valid		
	Calibration sticker is available for all keys		
Scrap Management			
	All tables for scrap should be cleaned every evening, inventory should be prepared accordingly		
	No pieces of scrap table for more than for two working days		
	On assembly line, no unidentified pieces can be placed (all isolated pieces should be identified using a sticker)		
Documents			
	File of meeting's minutes is available at the desk of G/L		
	Meeting's minutes include all modifications of JES, instructions, follow-up of all action plans and implementation		
On job training			
	Multi-function file should be updated : I verify that all my members are qualified /trained and files are updated		
	Rotation table is standardized and updated		
	Training records of all members is updated, for all the concerned processes		
	Training material for on job training is identified		
	Training is provided thoroughly (test for all check point including JES steps)		
5S Audit			
	Follow-up of 5S is displayed, in case of poor results; the G/L has added the appropriate actions. The assembly line is cleaned and compatible with 5S audit		
SPC charts, process & tools verification			

	Follow up plan is available		
	Tool record is present and updated regularly. G/L & A/M regularly verify the record		
	For each equipment, (PokaYoké) PKYK the control sheet of incident control is filled		
	SPC charts are properly filled and values obtained are in the tolerance limit. TL & GL regularly verify these charts		
	Measuring instrument (torque wrench, balance) are calibrated and sticker verification is necessary.		
	Re-calibration of each equipment after each incident (fallen, broken, repair...) is done		
	All types of anomaly is recorded and commented (values exceeding the tolerance, variation, dispersion between team values)		
Divers/Display			
	All notice boards are updated, all documents have a date and are valid		
	The repair activity file is available including all engine number with necessary details		
	All security points are identified. Security zone with regulatory measures are strictly forbidden (break oil filling, ..)		
	The intermediate stock is well identified with <i>Kanban</i> , piece utilization, key point designation		
Non conformities			

Table 6-8: Internal audit questionnaire

6.6.6.5 Training on Environment Management System (EMS) (ISO 14001)

The reason for the EAS focus on EMS was to make all employees aware of their responsibilities concerning environmental policy of organization. Some complaints were reported to the EMS team concerning the sorting of waste material bins. After inspection, it was found that the sorting of bins was not respected according to the established rules. Some metallic pieces of the engine were found in the bin reserved for plastic materials of the engine. So it was considered essential to communicate the sorting rules for each bin again. All containers contained an A4 size sheet with a photograph of concerned waste and the name of the waste to help all employees about its correct usage. Later, a training session for all the EAS members was conducted by the EMS team. In this training session, environmental policy of the organization was explained and the EAS members' responsibilities were identified to improve quality awareness on these issues.

Quality awareness is a responsibility, a privilege, and a commitment that requires employees support and involvement. This awareness is helpful in ensuring that one's job is done in ensuring quality aspects.

6.6.7 Database creation to monitor engine repair activities

Several non conformities were found concerning the recording of and follow up of engine repair activities. I talked with GLs of the EAS to explore the ways how the EAS can improve the quality of repair done at the engine assembly line and maintain record of all repair done. I asked him how verification and analysis of these repair activities were done. He showed me the follow-up file which was designed using an Excel sheet. This format was not very effective because it was developed for one week only. Therefore, every week one had to create a new sheet, and in addition, it did not include any past information of the last repair or the key information of last week. Indeed, this sheet helped the engine assembly to evaluate the defects, this is necessary information, teams that are responsible for the defects but without the repair of defects carried out, etc. After discussion with management, it was decided to develop a small database on Access

to monitor these repair activities. Access is a useful program to create and manage small sized databases. It has many built in features to assist users in constructing and viewing different pieces of information. I started working to create that data base using Access with the help of TLs and TMs who actually use this Excel sheet. All the required specifications were considered. The objective was to capture all the data of the EAS repair activities and to ensure the follow-up of data and to analyze these activities. I defined all the necessary fields for any type of repair within the EAS including:

- The number of repaired engine and date of repair;
- The name of the person who carried out the repair;
- The zone and team which is responsible for the generation of defects;
- Type of defect generated in the engine;
- Type of repair carried out to eliminate the defect.

Analysis of several simple data surveys was done in order to provide quick information including weekly defects, team defects, zone defects, graphical representation, and repair details. The data base allowed viewing of the defect activities with details. The database created was a big success as it helped the group leaders to analyze all repair activities. Moreover, graphical representations in the database helped them to present the data in their meetings and to improve the nature and quality of repair activities held at the engine assembly line. The major windows of the data base are shown in the appendix 1.5.

At the same time, I created a daily repair activity report for management to see all repair activities. Reports were made which presented the problems and defects of engine assembly parts. The report made it possible for the teams to quickly check the significant repair during the assembly. It was then included in the permanent reports to be sent to top management and the Japanese coordinator. It focused on the quality assurance of repair activities and minimizing the numbers of defects when the team members assembled different engine parts.

6.7 Conclusion

This study was basically an attempt to answer the research issues concerning the quality elements and implementation on a QM standard in the industrial environment for which *Toyota Motor Manufacturing France* was selected as a case study. This research cannot fully provide a final answer for the above research issues posed, however, it served mainly as an initiative for conducting a detailed case study to understand QM implementation. While the case study provides some analysis about the applicability of QM elements and the implementation phases in the EAS, the research work is geared towards maintaining some research hypotheses. After an evaluation and assessment process to identify the weaker areas of the organization's QM elements, QM implementation phases for ISO certification, various improvement action plans were proposed. From the above explanation of the organization's existing QM, it seems clear that the organization did not fully acquire and deploy the QM elements and QM implementation phases to achieve ISO certification. Therefore, it can be concluded that the case study organization had partially implemented QM. It can be further observed that the organization was leading towards QM implementation that could enhance a better image and quality brand. The quality evaluation process towards improved action plans was to assist the organization in offering a great deal to improve the current quality elements and QM implementation. Since the organization was willing to work on the evaluation report for improvement, the improvement propositions were established and proposed. The management of the EAS agreed to follow the improvement plan in order to achieve full implementation of QMS. Therefore, it can be stated that our understanding of the organization's QM implementation to evaluate the organization's quality elements, QM implementation phases for ISO certification, description of weaker areas and serving the organization in developing the improvement plans was applicable for TMMF. Thus, it is concluded that the QM implementation elements conceived and developed in this study is applicable to this organization. It is stated that the top management played a significant role in the process of QM implementation especially, quality integration and quality in everyday phases involving all employees.

6.7.1 QMI for the automobile industry

The next question appears to be if this QM implementation study can be used in other industries? As a matter of fact, this case study presented here was conducted in the automobile industry in France. Uncovering to which degree this study can provide the general dimensions to be customized as a part of an organizational QMS would require a detailed analysis in other business areas or departments. Strictly speaking, the generalization was limited. However, before going on to generalize the proposed study, it is better to go through other organizations. According to the principle of continuous improvement, it can be concluded that hardly any organization has fully implemented the QM implementation in practice. The approach followed in this case study was based on identifying QM implementation in weaker areas of the existing system and then lead towards improved action plans. It can be concluded that at the very least this study can be generalized for the automobile industry. Now a study is needed to develop the generalization for other industries, another case study was accordingly conducted in another industry.

Concentration on the communication-to-inform process experienced by employees during the implementation including all the steps like quality integration, quality in everyday use and quality system evaluation with the involvement of all employees not only helped them to provide a culture of awareness about the quality but also developed an environment of quality. The successful certification helped workers to realize their importance in the system and to adapt themselves as an integral part of the quality system. The quality triangle definition (policies, standards and guidelines, and procedures) was understood, including at the level of blue collars posts.

6.7.2 Improvement areas

The improvement areas identified focused on training, documentation, communication, multi-skilling and employee participation in the process management and top management responsibility. These are critical parts of the

QMS because they capture the combined impact of quality training and communication. The real problem solving suggestions were proposed by employees who were closest to the problem.

The study reveals that the provision of a culture of awareness through quality integration, its everyday use and suitable training for all employees play an important role for implementation of QM and to maximize employee development. All members have an important role and many have a direct influence on the quality of the product. A great emphasis on the training of all members is required in which communication-to-inform process plays a vital role. Organizations implementing QM are required to train large numbers of employees in quality issues. Indeed, the training with communication-to-inform process provides support of the transition to QM and employee skills. It is only through suitable preventative training that each member can fully understand their role in the production process. Training combined with experience allows each member to look for better ways to carry out their responsibilities, so that the organization can achieve its objectives. We found that a culture of awareness on quality issues reinforced the robustness of the team for better efficiency and quality of service, using all available resources.

It is predicted that QM implementation would be associated with a culture of quality awareness, and that this awareness would become increasingly group and developmentally oriented with the passage of time. As the implementation moved forward, testimonials from team members appeared to support our understanding on QMS and our hypothesis - less the phases of QMS implementation accompanies a QM standard, less the problem of the QM implementation is solved. Comments included: “the QM has increased lots of paperwork and improved our process management and assurance to do the thing right” and “our processes are better off with QMS; you don’t have to work in atmosphere of doubt about things or rely on one’s memory”. SPC verification also received much praise with one TL citing how he was able to view the process stability and work out a plan of action with a specialist within minutes after seeing SPC charts because both he and the specialist were able to look at the chart together while discussing the variation over the history mentioned in the chart. It is also assumed that time constraint did not allow me to see the after effects of ISO

certification that were required to be observed in order to improve the model proposed in the QM Modeling chapter.

Since the QM has only been in use for approximately 18 months it is possible that these kinds of development in terms of QM implementation, and improvement changes may occur in the future. However, it is also possible that certain elements of the QM implementation and utilization exert a stronger influence than those elements we considered, and those other elements led to an increase in the QM implementation. For example, while the organization's members were working intensively for the QM implementation and ISO certification, they were not given a choice about whether or not to use this QMS.

The central finding in the study discussed above was how the quality elements tie into and should be aligned with the organization's strategic directions to fully implement QMS. It should be mentioned that quality development begins and ends with mutually informed people. With this strategy, an involved top management guides people to improve their ability to meet expectations of a high quality. QM implementation is an excellent approach for making improvements and enhancements in all processes. A worker, who knows the concept of quality, can best apply it while working at the grassroots level. Top management is of critical importance as it focuses on overall strategy to involve everyone in the organization. The strategic implementation is required to communicate in all dimensions of organizations. No strategy or standard can be implemented without constant focus on communication. Such communication involves strategies like knowing which "new and important" ideas and message, *i.e.* information, is required to be transferred to which actor of the QMS. A quality department can communicate without informing, this remains a barrier to implementing the QMS in the organization. So, communication to inform is crucial especially in initial phases of implementation when employees are not in aware of the QMS. QM implementation requires crucial informational skill to provide directions to teams, relay timely pieces of information to and from one top management to employees to manage the whole process in the desired way to achieve the organization's objectives.

There are several lessons that can be extracted from the study presented here. The first is that nothing happened until we began to focus on QM implementation; until we were committed to measure and understand the quality integration and its everyday use that is vital to improving the existing processes through a quality system evaluation. Here one can see an advantage from the case study organization's approach of *Kaizen* that leads to continuous improvements. The second is that we need to invest and concentrate more on humans than other parts of the system. Because all resources required making the process run and technology acquired is in the hands of people who are using these resources. Once people involved in the process are asked to make improvements, the changes they proposed are easier to implement rather than engineering changes that sometimes require engineering investment and can be complex in nature. So, it is much easier to implement and workers adapt themselves accordingly because these are proposed by them. The low level of QM implementation was due to poor communication of relevant information. In fact, misinterpretation of the QM design, misunderstanding of the proposed standard, or failure to act according to the standard are the result of broken links of communication, notably when there is no, or inappropriate information. When a system is documented but not implemented a major force can be broken down in communication that battles to pass the appropriate information to the right person at the right time.

QMS implementation is a collective rather than an individual activity so one can emphasize that quality progresses in situations where individual lessons must be a shared and structured approaches are followed. For this purpose, QM should be seen as an informational process for all employees that will lead to implement quality standards in the organization. This process along with timely training is helpful in the acquisition of and development of shared vision towards QMI. QM as an informational process should always be supported with trainings to enhance the chances of success of implementing strategy and improve understanding of implementation. This is a continuous process of awareness to help the organization achieve QMI. QMI should not be taken as the sole responsibility of the quality department. However, the quality department is required to ensure that all information about QMS are received and understood clearly. It can be concluded that organizations should strive to promote awareness

in routine activities. Creating a cooperative atmosphere for QM implementation should be seen as an inseparable part of the quality system. When creating a culture of awareness, quality teams have the duty to seek a common quality vocabulary to be understood and understand the department's context where quality standards are required to be implemented. As more organizations understand the culture of quality awareness philosophy they will incorporate it into the QM programmes. Awareness on the quality system is a problem solving approach and requires quality integration tools and everyday use for standardization. As a tool, a culture of quality awareness embraces common quality vocabulary, assimilation of a QM system, perception of the same system for all to provide suggestions for the system, etc. It is said to drive competition for the sake of competing, and once an environment of awareness has been established ending it is not an option. A culture of quality awareness calls for managers to evaluate criteria such as discipline, skill development, participation, involvement through successful communication. These explanations and basis for quality awareness of QM implementation emphasize that it is truly something that involves every worker at every level.

One purpose of QMI is to compile experiences of the team effort and communicate them to management for future improvement. The data collection from the site regarding the effectiveness of the technical process, and the quality aspects of activities can identify areas for future improvements in any of these aspects. The conclusion phase provides an effective means for communication between teams and management that is necessary for performance evaluation and improvement. This approach supports everybody's commitment along with top management as feedback mechanisms. Moving towards a culture of quality awareness for continuous changes is much harder to effect than technological change. The top management must be recognized as the leader of the QMS and responsible for creating a culture in which the QMS can be effective and assure compliance with a documented QMS.

While concluding the findings of this study, it is to be mentioned that less the QM is accompanied by quality elements, less the problem of QM implementation is solved. Thus, QM elements affect QM implementation phases.

7 Case Study 2 – *Sanofi Pasteur*

7.1 Introduction

Case study observations about implementation of QM in *Sanofi Pasteur* and understanding of QM process had an important role in this research. The conceptual framework (presented in chapter two, three and five) helped me to understand the key concepts for QMI in this case study and to examine the implementation process while working very close to the industrial department in the organization selected for this case study (*i.e.* quality and validation department). This case study was an attempt to gain a better understanding of QMI phenomenon. This chapter describes the second industrial case study. Section 7.2 presents the research methodology adopted in this study. Section 7.3 discusses the relationship between first and second case study below. Section 7.4 presents the introduction to the organization and description of *Information Solutions (IS)* departments, its processes, different teams and the role of the quality department - *ISQV*. Section 7.5 identifies the key elements for improvements in the QMS of the case study organization. Three major elements were identified including *IS* quality manual, Computerized System Validation (CSV) and file management. Details of the CSV and CM were presented in chapter five. File management is described in section 7.8 with some proposed recommendations. *ISQV* Intranet is presented in section 7.9. Evaluation of quality elements is discussed in Section 7.10 along with QM implementation evaluation that is mentioned in section 7.11. The conclusion of the case study is presented in Section 7.12. List of all preliminary terms used in this case study is presented in appendix 2.1.

7.2 Methodology

The presented case study was conducted to observe the QM implementation in the pharmaceutical industry by participating in writing a quality manual as a reference to *IS* quality system procedures. This section provides the methodology for this case study and *IS* organization details. Then the research strategy is presented.

7.2.1 Sampling

The pharmaceutical industry in the Rhône Alps region (eastern border towards the south) of France was selected for investigation due to its vital industrial position in France. The case study involved the data collected for three teams (business, platform and infrastructure, operations and services) working in the IS department. Thirteen team heads were involved and 30 members participated in this study from the IS department who were involved in different QM activities. A web based survey was also conducted for which the number of participants were 144 from *Sanofi Pasteur*. Details about this survey are presented in section 7.8. For the purpose of this study, the quality elements were considered in order to observe QM implementation.

7.2.2 Case study process

The study was carried out in the IS department of a multinational pharmaceutical organization's site in France, Lyon, in the years 2004-2005. At first, I proposed the aim of conducting the case study to the organization. The quality and validation management and human resource (HR) department were contacted to arrange a research coordinator to help me for the analysis in the case study organization department of IS. The Deputy Director of the *ISQV* (Information Solution – Quality and Validation) was asked to deliver a general introduction of the IS department, relevant quality activities, organizational structure, etc. In addition, I planned a quick guided visit of the case study organization with the aim of being familiarized with the working environment, QM activities engaged, major processes, etc. As the pharmaceutical industry was relatively unknown to me in terms of quality practices, I took help from *ISQV* teams to collect relevant information about IS. These meetings with *ISQV* seemed to be beneficial in collecting quality information about the case study organization (history, current QM implementation practices, annual sales, overall business performance, the organization's yearly working reports, rules and regulation, regulatory authorities and imposed international and regional health laws and implementation, etc). The next major step was to gain understanding of QM in the

IS department to observe the QM implementation. The *ISQV* head described quality regulations applicable to the pharmaceutical industry in the *IS* domain. Three major fields were identified including quality manual, CSV and file management to lead towards QM activities. I was provided with the necessary details (regulatory authorities requirements, applicable laws for *IS* department, compliance strategy for audits, etc.) to understand these areas. After intensive work of four months, I was able to have a reasonable understanding about CSV and CM. During this period, I tried to observe and understand the QMS through discussions and recommended documents. Key areas for improvement were identified as CSV and file management. After the identification of the weaker areas of the existing QM system, an improvement plan was established with an objective to improve QMS and deploy best practices. The *ISQV* head was constantly contacted in order to make the improvement plan applicable.

7.2.3 Case study description

The primary objective of this case study was to provide a case example that could be used to observe QM implementation in grassroots practice. However, due to time constraints and practical ease to work with the organization, this case study organization was asked to assist me in providing support for accessing the QMS of the organization. This case study industrial environment was different from first case study, with different applicable regulatory and conformance conditions for QMS, so total replication was not possible to match this industrial case study with case study 1 of *TMMF*.

The detailed discussion in chapters 2, 3 and 4, demonstrated the crucial role of top management in the implementation process of QM through involvement and commitment. A meeting with the deputy director of *ISQV* and the HR Manager resulted in the organization's willingness to conduct the study. Moreover, discussion with the *ISQV* head and the *IS* vice president paved the way to provide necessary support for the case study to be conducted in the organization. In addition, top management helped me to access the necessary information for the study and to approach concerned people of the organization. An *IS* quality analyst

from the quality department provided me the support in various places to conduct the study, and he explained the history of QM implementation in the *IS*.

Many organizations use a defined set of practices with established business vocabulary to work and this should be communicated to all employees to implement the organization's norms [104]. I participated in several training sessions in order to understand the FDA audits, CM, CSV and regulatory requirements. The aim was to attain a satisfactory understanding about the organization's quality vocabulary.

The methodological approach towards formalizing the CSV process was done to standardize the validation process of the entire computerized system. It was among the improvement plans that was discussed and approved by the IS top management to work for a QMS. In addition, improvement in CSV methodology were developed with the help of *ISQV* teams, editors and reviewers of the *Handbook of Research on Informatics in Healthcare and biomedicine*, and the *Handbook of Research on Distributed Medical Informatics and E-Health* who offered valuable suggestions, before the book chapters were published by IDEA Group Publisher, USA in 2006 and IGI Global Publisher, USA in 2008. Furthermore, the *IEEE (The Institute of Electrical and Electronics Engineers)* IEEE offered a great deal in providing suggestions in a CM approach that was published by the IEEE International Conference in Ottawa, Canada in 2006.

An important step to evaluate the QM implementation was done with the help of the *ISQV* deputy director who was the focal point in FDA official audits for information system of the organization in France. Various audits were observed to obtain an improved understanding of the existing QMS of the organization. Then some improvement plans were provided. Weaker areas were considered as the main source for improvement. Due to the time constraint, this case study covered only some practical aspects of implementation of the improvement plan. Thus, the after-effects of successful implementation were not observed in detail.

7.3 Relationship with the first and second case studies

In the first industrial case study at *Toyota Motor Manufacturing France*, the study dealt with a QMS implementation of ISO certification whereas this case study deals with QMS improvements of a computerized system. ISO and CSV share many common values however; the restriction of CSV is more in terms of regulatory requirements from health authorities. Moreover, the organizational context, objectives, goals, environment, and business do not fall in the same category. Nevertheless, a possible relationship between the first and second case study can be presented as:

Case Study 1: *TMMF* - QMS implementation with the help of ISO 9000 certification in the automobile industry engine assembly line;

Case Study 2: *Sanofi Pasteur*: QMS implementation with the help of CSV in the pharmaceutical industry information system.

In both case studies, our focus was on observing the quality elements and QM implementation.

7.4 An introduction to the organization

Operating in over a hundred countries, *Sanofi-Aventis* markets major pharmaceutical products derived from its research and a very wide range of medicines adapted to local needs throughout the world. *Sanofi Pasteur*, the vaccines business branch of *Sanofi-Aventis*, is the largest company in the world devoted entirely to vaccines. In 2004, *Sanofi Pasteur* produces nearly a billion doses of vaccines, making it possible to protect more than 500 million people across the globe, which is about 1.4 million vaccines per day. *Sanofi Pasteur* is producing vaccines at four major sites: in France in Marcy-l'Etoile or *MLE* (near Lyon) and Val de Reuil or *VDR* (near Rouen), in the U.S. in Swiftwater (Pennsylvania) and in Canada in Toronto. The case study was conducted in *Sanofi Pasteur* headquarter in France which is located in Lyon abbreviated as *CFL*, in the east of France, and was among the backbone organizations in the country in manufacturing vaccines. The organization has been implementing QM for long time and regularly revised its QMS in accordance to the regulatory authorities'

requirements like FDA, AFSSAPS and Health Canada. Due to its effective vaccine business, the organization was reputed as a world class organization in the pharmaceutical industry. It consolidated sales of 25 billion euros and 4 billion euros research and development expenditure in 2003. In 2003, the organization had about 100,000 employees in the world.

Information Solutions (IS) developed and maintained the information systems with a mission to provide the *Sanofi Pasteur* technology customer with a single point of contact for all information technology needs and requests. The IS Management provided the organization's users all the necessary information solutions allowing the effective communication-to-inform process between the various sites of *Sanofi Pasteur* (servers, network, etc...) and to connect to the external world also (Emails, Internet, etc...).

The IS organization consisted of several platforms, process areas of *Sanofi Pasteur Information Solutions* in Canada, France and the United States. These include: Research and Development; Industrial Operations; Business Support; Commercial Operations; E-Doc Platform; Infrastructure; Customer Service; SAP (System Application Program) SAP Platform; Web Platform; Wisdom Platform; Project Management; Network and Telecom & Security (NA); Support Functions (FR); Data Integration (FR); Quality and Validation; Strategic Planning; Systems and Servers.

Each IS Process Area and Platform was required to understand the existing quality system, to write their procedures, and to provide input to the (*Information Solutions Quality & Validation – ISQV*) for the continued development of the quality system. These teams contacted *ISQV* and seek guidance to:

- Assist their team in the implementation and application of IS quality and compliance processes *i.e.*, (change management, computer system validation, and training).
- Assist *ISQV* in providing validation and quality guidance/training to their team.
- Act as a vector of the quality improvement of their team.

IS relies on business users to help define priorities, user requirements, testing strategies and the associated documentation to support the systems development, implementation and maintenance activities.

7.4.1 IS organization

The IS organization was composed of three major types of teams including business, platform and infrastructure, operations and services teams explained in *Figure 7-1*.

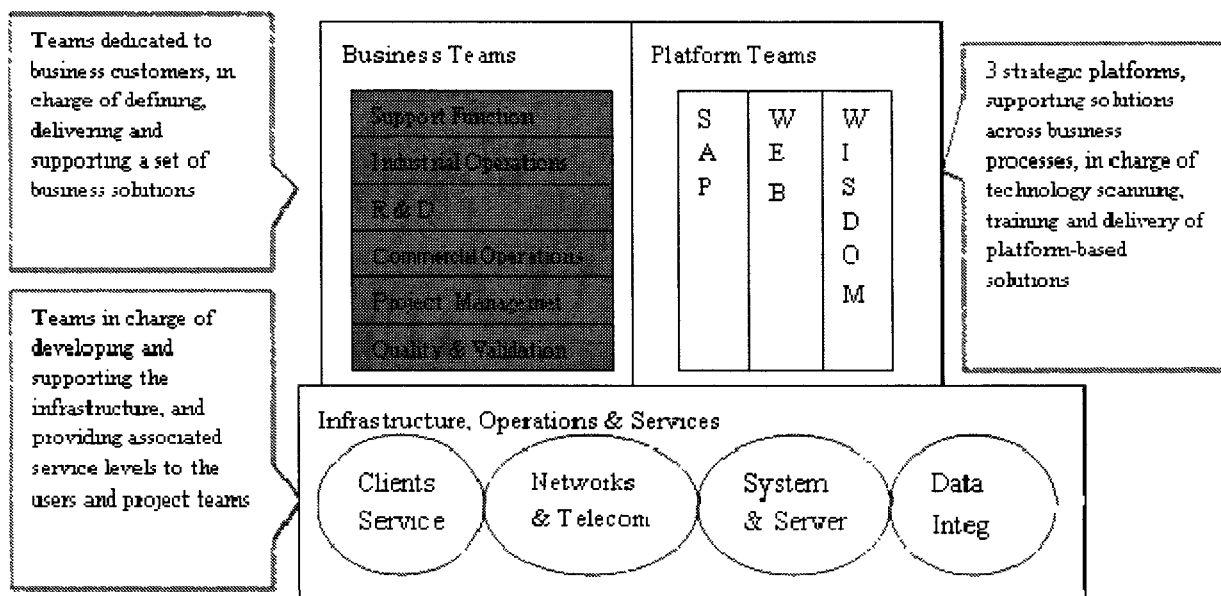


Figure 7-1: IS organization

The IS organization was operated internationally as a unified company through global functions and initiatives, while ensuring efforts were locally united in France and North America. At the international level, unity was maintained by a common mission, vision and strategy. At the local level, the local management managed the business and, played the vital role in managing support services and facilitating interdependencies between functions located in their countries. *Figure 7-2* shows the organization structure of the *ISQV* team.

7.4.2 ISQV (Information Solutions Quality and Validation)

The team did not exist before 2004. It was created to support quality and computer system validation activities by top management initiative in 2004. Before, the Industrial quality team, which was located at MLE (Marcy l'etoile) site, was responsible for both the industrial and headquarter's computer system validation activities. The *ISQV* team was committed to promoting quality activities in the *IS* environment. Its objective was to ensure internal customer satisfaction, business efficiency and regulatory compliance. The *ISQV* helped different *IS* teams and users to meet the quality and validation requirements for the computer system lifecycle and by defining and maintaining compliance policies, standards and guidelines. The *ISQV* priorities were the compliance of the *IS* solutions and the quality of *IS* processes. The *ISQV* activities are presented in *Figure 7-2*.

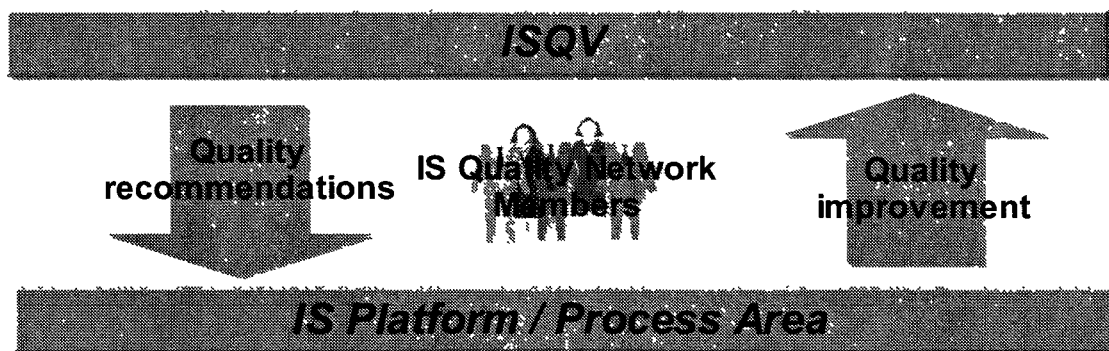


Figure 7-2: ISQV activities

7.4.2.1 ISQV major services

ISQV services supported business users projects, *IS* various quality activities and *IS* technical services by implementing quality practices like:

- *IS* representative in the Sanofi Pasteur quality initiatives: All policies and standards, *IS* validation strategy and *IS* quality improvement plans were initiated by *ISQV*. *ISQV* ensured that quality systems were in place, integrated into *IS*, and that the procedures were understood and followed;

- Computerized systems validation: Management of the validation dossier; providing of guidance and assistance for the validation strategy definition, vendor audit, review and approval of validation deliverables;
- Audit: Conduct and lead the internal audits and regulatory inspection of IS department processes, systems, operations, and procedures to assure conformance with related regulatory requirements or internal standards;
- Training: Computerized systems validation, electronic signature, operational qualification execution;
- Change management: Supported IS teams for qualification and analysis of changes, leads of CM board.

7.4.2.2 Some facts and figures

- Geographical perimeter: All computerized systems
- Domains: All regulated IS domains
- Systems: 60 validated computerized systems
- 2000 Change requests a year
- Ensure processes are in-place for handling, responding, and closing observations to external assessments or audits of the IS Department.

7.4.2.3 ISQV organizational chart

The *ISQV* team consisted of four people in France and six people in North America, which were specialists in validation of computerized system and quality. *Figure 7-3* outlines the *ISQV* organization chart in December 2005. I worked with both teams (France and North America).

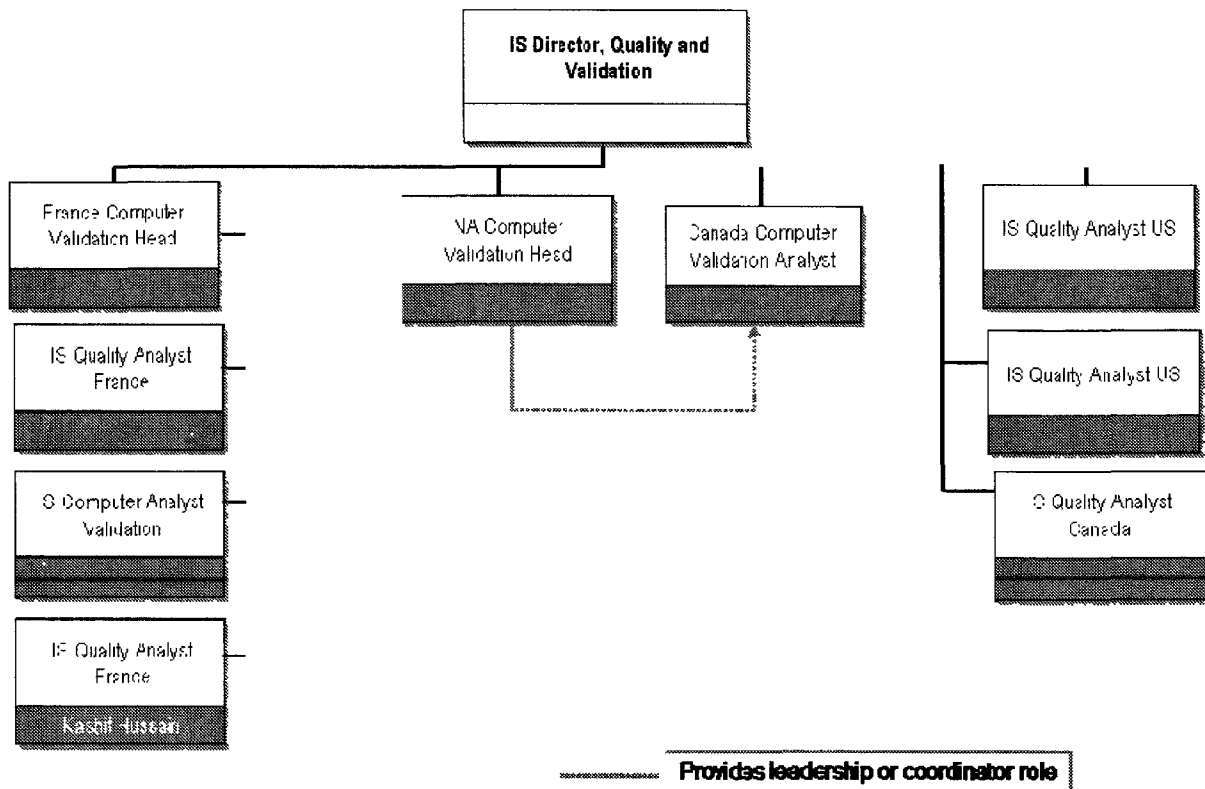


Figure 7-3: Organization chart of ISQV at Sanofi Pasteur in December 2005

7.5 Identification of key elements for improvements in IS QMS

The major source of evaluation was the audits proposed by regulatory authorities and which were scheduled on a regular basis. Thus, a quick evaluation list was observed from the audits of the mentioned areas for improvements after discussion with the *ISQV* team that was responsible for regulatory audits in IS. Moreover an additional step was added which was the *IS* quality manual participation to improve the understanding of the organization. The purpose was to support various solutions in maintaining IS applications and computer systems by ensuring quality and compliance which was the major purpose of implementation of QMS in an IS organization. I identified areas for improvement with the *ISQV* team and was involved in the following areas:

- Quality Manual for the IS organization:** The QMS rules usually reside in quality policies and manuals. I wrote 10 sections of the quality manual of the IS department which was used to provide the first guide to the quality

auditors. I used this opportunity to understand the pharmaceutical industry's QMS. The manual was finalized in September 2005 and I was among the major participants and played the leading role in the French team with the help of quality and validation experts of the *ISQV* team. The manual was then used to provide to all new employees information about the *IS* departments and its functioning.

- **Development of global methodologies for the IS organization:** The QMS understanding was not at all possible without knowing the different methodologies adopted and proposed by *ISQV* like the Computerized System Validation (CSV). I participated in developing and finalizing CSV methodologies including change management (CM) methodology.
- **File management improvement plan:** Document management is among the necessary elements of QMS that formalize various types of documentation. An improvement plan on document management for some tools was taken in order to provide some recommendations for use in the *IS* department. This improvement plan engaged several actors and was done with the collaboration of *Accenture* Consultant Company in a project “file management”.
- **Improve communication of quality activities through the intranet:** Usually the Intranet is considered as the job of the web team. I provided constant support to design the ergonomics and development of the site contents of the *ISQV* Intranet that was then approved and is still being used.

The brief description is presented in the next section to provide the reader with a clear vision of these topics.

7.6 Quality Manual for IS organization

The quality standards and rules enable an organization to effectively adapt to the required standards. All the applicable standards and rules exist in the form of quality policies and manuals. The quality manual is considered to be top tier (level one) of QMS documentation presented in *Figure 7-4*.

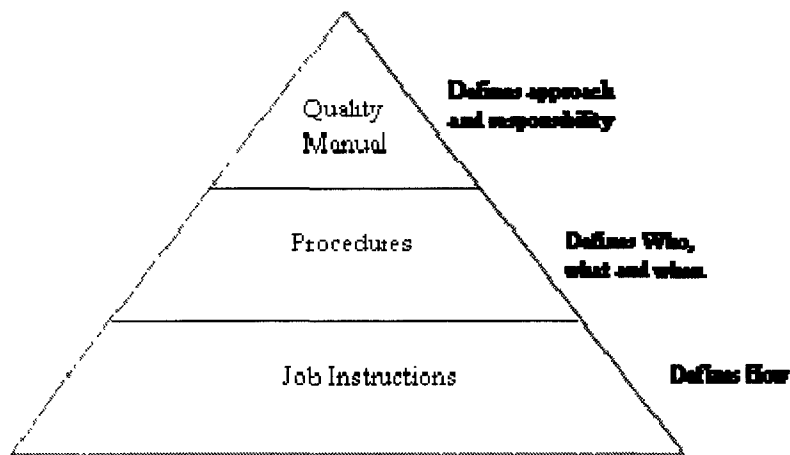


Figure 7-4: QMS requirement for the documentation

Why a quality manual: The quality manual helps the *IS* teams know about the *IS* approach and responsibilities. The quality manual provided *IS* employees an overview of the *IS* quality systems. This was considered as the first improvement plan with a dual objective. For me, this quality manual was helpful in knowing the organization's business and norms. The second objective was to provide this manual as a reference guide for existing *IS* employees and a starting point for auditors as an overview of the *IS* quality systems, an orientation guide for new employees to understand the organization's quality processes and also a tool for the *ISQV* to identify quality process improvement opportunities.

The quality manual's composition: The quality Manual was established to define the policies and procedures used in the *IS* organization to ensure customer requirements, needs, and expectations are met in the light of the organization business objectives. The policies and procedures contained in the quality manual were intended to establish and communicate the minimum requirements that all operating departments of *IS* must meet. These requirements were based on the applicable regulatory authority's standards. The major focus on writing the quality manual for the *IS* department was to include a critical approach and responsibilities for the *IS* teams, regulatory requirements applicable in USA, Canada, France and EU and to present how the *IS* organization was working.

The QM reflected the *IS* commitment to implementing the underlying system in order to improve, ensure and maintain the *IS* quality standards. I worked on several parts of the *IS* quality manual in collaboration with *ISQV* teams in

France, USA and Canada. The quality manual provided reference to the quality system procedures and outlined the structure of the documentation used in the quality system. An extract of some sections of quality manual is presented in appendix 2.2. The participation in the quality manual was found helpful in observing the QMS approach and strategy which the *IS* departments adopted in taking part in QM implementation. It assisted me to absorb and capture necessary quality vocabulary and language related to the pharmaceutical industry.

7.7 Computerized System Validation - CSV

The general methodology of CSV is presented in chapter five. As explained in chapter five, the major purpose of this methodology was to assure the quality and compliance requirements and considerations with all deliverables of a computer system and its use in compliance (functional, reliability, integrity, security requirements, operation and maintenance) with the applicable regulatory requirements. The CSV is based on the concept that all risks are well managed and a computerized system is prepared against all risks.

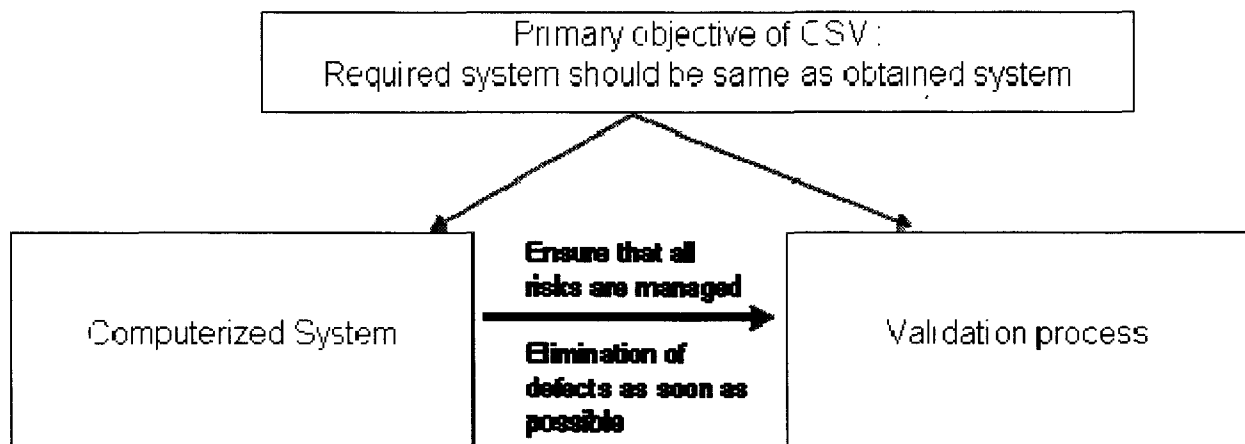


Figure 7-5: Objective of CSV and approach towards system

All the steps for the validation life cycle must be documented. In establishing the CSV methodology, the major focus was to consider all the possible parameters necessary for the validation. As discussed in chapter five, CSV asks for complete and thorough documented procedures for QM in the form of documentation control, records, audit, corrective and preventive actions to remove non conformities etc. The extent of written documentation is defined according to the size and type of a computerized system and depends on the

complexity and interaction of processes and associated risks. When the CSV process was explained to all IS teams, people were asked to engage in writing in the way in which things really happens in practice. The following approach was used in all the training sessions and workshops.

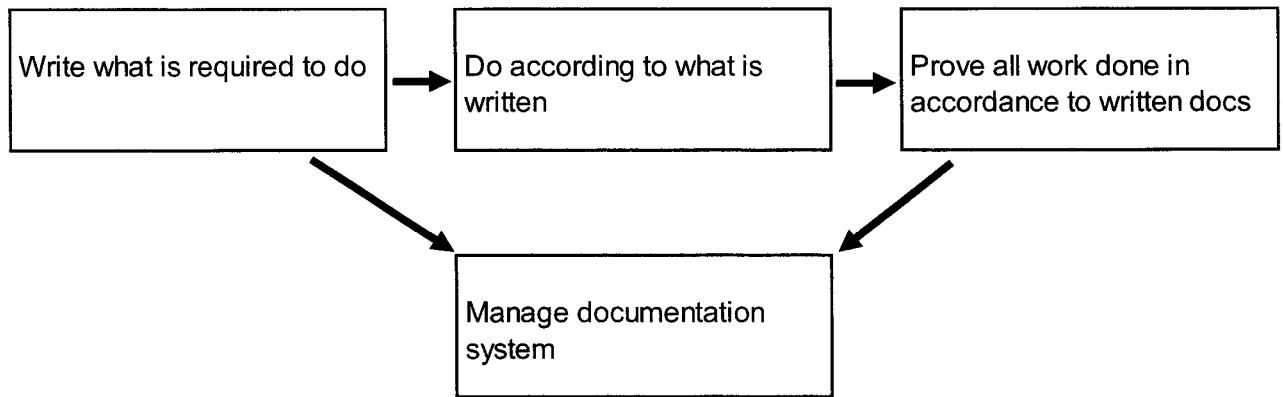


Figure 7-6: How work should be done in accordance to documented QMS for CSV

In addition, a responsibility matrix was defined including all the risks levels, system and IS parties involved for each validation step. Various evaluation forms and guidance documents and template (*ISQV* project evaluation form, IS validation plan form, IS installation qualification form, IS system release verification form, IS deviation form and IS phase release form for operational qualification, risk analysis matrix, traceability matrix, change management request form, etc) were added in the IS CSV procedure. All supporting documents were found helpful in improved understanding towards the validation process. The major objective of these template guidelines was to provide a mutual understanding of the validation process.

7.8 File Management

Today, the organization's document management practices are among the important businesses to handle. This is due to a large part to stricter legislation and compliance regulations aimed at securing and archiving critical information. The documentation has, for a long time, played a key role in the field of QMS. The handling of data stored in different applications and tools has been a primary factor in documentation. Numerous applications have been developed to organize, maintain and search documents or files. In recent years there has been a growing

demand for an effective information system owing to the ever-increasing capacity to generate, use, share and reuse information. The result functionally is ‘too much information’ [201] [367]. It is important to manage these file management tools that support collection, publication, sharing, storing and preservation of information in a variety of ways in *Sanofi Pasteur*.

This part of the thesis is based on a study which I developed while working in collaboration with *Accenture* consulting company on the project “file management” of the IS organization of *Sanofi Pasteur*. The project resulted in the recommendations for better utilization of tools used for different files categories in *IS* departments. These tools include public folders, *shared folders* and eRooms and Intranet.

During 2003-2005, IS documentation was (stored in public files, eRooms, Intranet and emails) increasing by 50 % each year. It represented (on a *Sanofi Pasteur* scale) 60 % of the total of stored electronic data.

The situation further led to certain questions like:

- Where should the IS documents be stored?
- Why does the organization work with a multitude of versions of documents stored for the long term?
- What can be removed/filed/archived?

How does one manage the information presented in these types of tools especially in terms when clear recommendations became essential to improve the performance of these *IS* tool? In order to propose an improvement plan, the project named “file management” was initiated, with a first phase focused on “IS documents”. The phase lasted 10 weeks and aimed at providing quick results and easy implementation, short-term actions and clear recommendations about the file management and associated tools. The information tools that were used to store IS documents are described in the next sub-section.

7.8.1 Assessment of the file management tools

In 2005, the non-structured data (public folders, file servers, shared folders) of IS (information solution) department grew at a rate of 50% per year and it accounted for 60% of data storage needs. I participated in the collaboration with the *Accenture* consultant company. The action plans were linked with the analysis of existing documentation, identification of people for interviews and discussions, kick-off meetings, and preparation for assessment and planning. The storage of data in the IS organization is presented in *Figure 7-7* to access the situation.

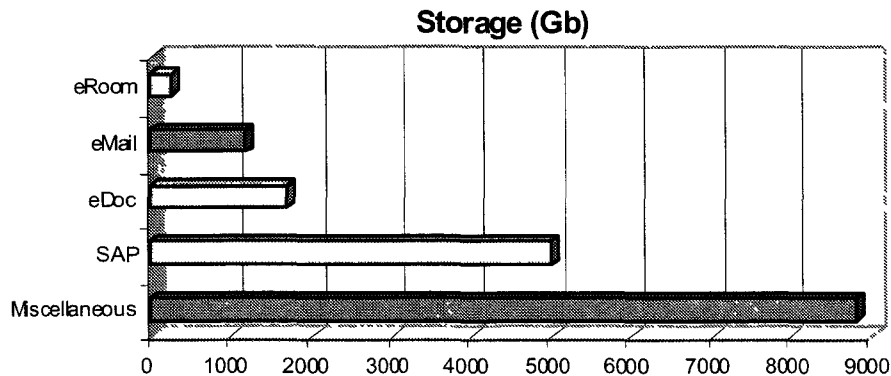


Figure 7-7: Storage by the year 2005 at IS in terms of capacity in Gb

Here we can see that non-structured data (miscellaneous) grew at a rate of 50 % in year. For this reason, it was considered important to improve the utilization of associated tools with non-structured data. In this improvement action plan, the focus was on the tools (shared folders, public folder and eRoom). It was observed that these tools were not fully utilized and some tools needed to be more specific concerning the usage policies. e.g.

- The intranet was underused;
- Shared folders were called into question;
- Public folders were about to disappear;
- eRoom was badly organized.

The description of facts and figures about non structured data in tools (public folder, eRoom and *shared folder*) that was used to analyze file management is presented in appendix 2.3.

7.8.1.1 Key Strengths and Weaknesses of IS tools

Various advantages and disadvantages of the tools were identified and are mentioned below.

Supports	Strengths	Weaknesses
Shared Folders	Easy to work with (intuitive) No training required	Not well structured Difficult to find documents No records tracking
Public Folders	Linked to emails Synchronized/Available during travel.	Easy to misuse with emails Difficult to use for document sharing Difficult to find documents No advance features (e.g. records tracking) Risk of disappearance
eRoom	Good collaboration tool (accessibility, alerts, chats, etc.) Easy to find documents Easy to track documents' life cycle – versioning.	Has sometimes technical problems Require training to fully optimize features Documents modification is a bit complicated
Intranet	Good storage place for tips & tricks Large scale communication tool	Difficult to find what you are looking for (structure and search tools) Require training to post documents / communication
Personal Folders	Helps create back up Personal (access restricted)	No search tool

Table 7-1: Key strengths and weaknesses for each tool

1.8.4 IS Survey for file management

A survey was also used to gather information on file management practices. This instrument was developed with *Accenture* consultant company after a careful review of the organizational need in terms of the QM issue. The participants were asked to provide answers about their perceptions of file management practices they were using in the organization.

Data were collected in multiple sites (France, USA and Canada) using the same questionnaire via the web. An initial list of items was generated through a detailed discussion with the *ISQV* and *IS* top management to provide guidelines on file management. The list was initially evaluated with the help of the *Accenture* principal consultants (US and France), the *IS* management director for file management project, and the *ISQV* department engaged in document management at the *IS* where the study was conducted. The questionnaire was divided into four parts:

- 1- Participant presentation (Q1:work place; Q2: working team);
- 2- Type of documents use (Q3:types of documents used for each tool);
- 3- Participant suggestion about file management effectiveness (Q4:best practices observed in organization; Q5: best practices to implement in the *IS*);
- 4- Working habits of participants and their knowledge on file management (Q6: knowledge about file management practices; Q7: knowledge about eRoom functionalities; Q8: suggestion about file management.

This list served to finalize eight questions, which were again evaluated by all teams (*ISQV*, *Accenture*, *IS* project management) to ensure that the statements were unambiguously worded. The results of this evaluation indicated that most statements were understood without ambiguity. Over 144 participants took part in the survey. The questionnaire was designed to provide a quick picture of the existing situation and required less than 15 minutes to complete. Details about the *IS* survey are presented in appendix 2.4.

7.8.2 Interviews with IS members

A series of interviews with 28 key people from all the IS domains in France, USA and Canada were held. These interviews were conducted by *Accenture* consultants. Seven major suggestions appeared in these interviews among which two were selected later for further actions. The reason for this selection was based on ease of implementation and importance for *IS* teams.

1. Clear files location identification;
2. Known records retention guidelines;
3. Dedicated file management manager with clear responsibilities;
4. Better search and archiving tools;
5. More logical files structure;
6. Better practices on versions tracking;
7. Reduction of documents segregation;
8. Better support to optimize available features (eRooms, Outlook, etc).

Among these suggestions, two were selected as quick results in the organization's context after finalizing with *IS* top management which include clear files location identification and more logical files structure.

In addition to these suggestions, various interesting facts were revealed during discussion with teams including the following remarks:

- What do you mean by file management? What is in it for me? What does the organization expect from me?
- eRoom alerts are useful, but we receive so many, we just delete them!
- We need a structure, governance, and rules and someone to assure compliance.

- The main problem here is that people do not clean up! If they would, we would know where to find what we are looking for!
- Tell me on what tool I should store my files.
- I have no idea of the space storage dedicated to my team, whatever the support/tool.
- Can we have better archiving & search tool?
- Public folders are obsolete and so huge that we cannot retrieve our files
- Can someone tell me what kind of document I should keep, for how long and what/when I can delete or archive?
- Emails are not an issue because there is a limit of space – people are forced to clean up!

Details of the discussion with IS teams including identification of various good practices and gaps, key straight and weakness, recommendations were identified which were mentioned in appendix 2.4.

7.8.3 File Management team proposal

Numerous suggestions were proposed to define guidelines and policies regarding file management in the survey and an interview (refer to *Table-13*). People were not aware of any file management procedures except quality documents. For using any tool of a document, there were no precise instructions available. It was found essential to dedicate a team for file management. The role of the new team was defined with responsibilities with the help of suggestions provided to improve file management activities. The team will be managed by the global administration team that will define guidelines and policies. The global administration team will be supported by an operational support team to analyze file management activities and policy deployment. A technical support team is helpful to ensure technical support for file management tools. A team manager will insure that his team is working according to the required file management policies.

He will be supported by key users of his team having advanced file management skills to facilitate the file management activities in his team and create a network with key users of his and other teams.

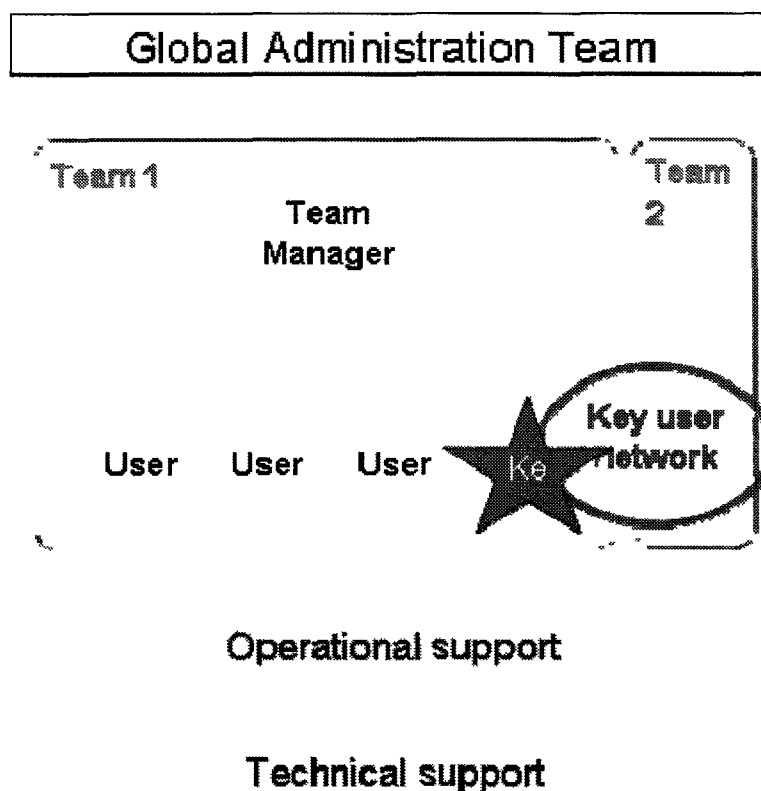


Figure 7-8: File management team proposal

Function/ Role	Scope	Location	Responsibilities
Global Administration Team	Central	Global	Define guidelines, policies and practices Define global file management, training and communication objectives Collect needs regarding tools improvements Organize and insure the control
Operational support	Central	Global	Reports creation and analysis (dashboard) Report to the Global Administration Team Insure the consistency of the file management structure (eRoom creation, etc)
Key Users	Local	Country	Strong and advanced file management skills Responsible for experience sharing (best

			practices, new comer) Facilitated by the global administration team
Team Manager	Local	Country	Make sure their team applies the file management policies
File Owners	Local	Country	Implement the file management for all documents owned
Technical Support	Global and Local	Country	Technical support of the file management tools

Table 7-2: Recommendations for future IS organization for file management

7.8.4 Files and tools location proposal

After viewing the *Table-14* proposed by IS teams, future location for each category of files was defined. It was modified in order to improve the utilization of different tools. We added eRoom for policies procedures, forms and templates) in the case of working documents. This is to help users save the working document in a structure tool before it is published. In eRoom, all previous versions are also saved automatically which is helpful for a user to consult a document before finalizing it. The same approach was used for communication (announcement, presentation, press release) to use eRoom for working and reference documents. Only reference documents were proposed for the Intranet.

Reference Documents	e-Room	Shared folder	Intranet	Outlook Email	Other
Policies, Processes, Procedures, Forms (Methodology, etc.)	W		R		
Forms & templates	W		R		
Project documentation (including Project budget, Plan, Requirements, etc.)	W/R				
Applications documentation (specification, test scripts, etc)		W/R*			
Training (users manual, list of participants, facilitator guidelines, etc)	W		R (NA		R (FR

			Users)		Users)
Technical items (including executables, databases scripts, etc.)		W/R			
IS General communications (IS announcements, news, etc.)	W		R		
IS Specific info (Presentations, press release, etc.)	W/R				
Team management/participation documentation (Budget, staff meeting minutes or similar document, objectives, planning activities, follow up)	W/R				
Vendor general info (vendor highlights, new solutions presentation, etc.)	W/R				
Vendor confidential information (Contracts, Service level agreements, etc.)	W/R				
Planning / calendars	W/R		W/R	W/R	
Personal documents		W/R			

Working and reference documents: W/R;

Working documents: W;

Reference documents: R;

* Shared folder then Documentum

Table 7-3: Recommendations for the IS file location for each tool.

This subsection presents the weaker areas of the organization's QM implementation and the reasons leading to these weaker areas.

7.8.5 Improvement plan for file structure

Two suggestions were selected as quick successes in the organization's context after finalizing with the IS top management which include clear files location identification and more logical files structure.

7.8.5.1 Guiding principles for IS file structure:

To improve file management, some steps were proposed which include:

1. Reduce files / information segregation between France and North America;
2. Ensure files structure homogeneity between regions (when possible and made by eRoom coordinators);
3. Reduce files / information segregation between domains and teams within a same region;
4. Maintain files structure homogeneity between domains and teams within a same region (when possible and made by eRoom coordinators).

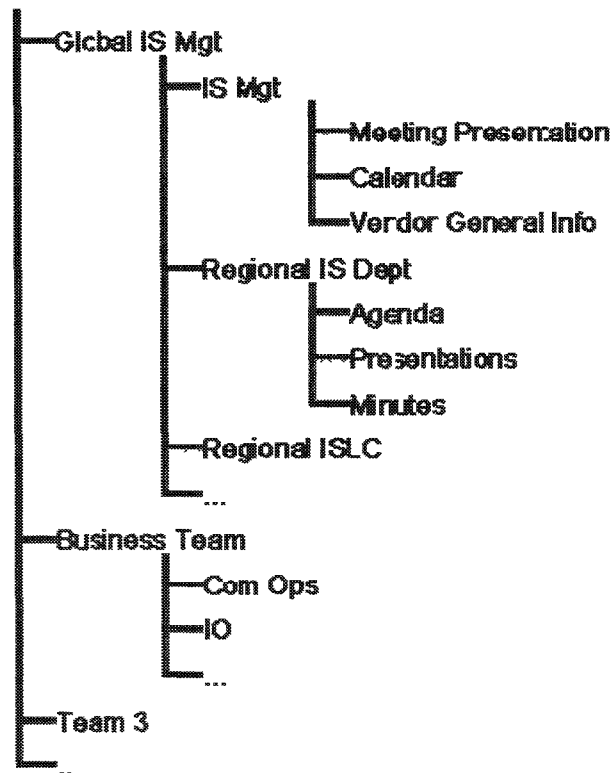
7.8.5.2 Recommendations for IS file structure:

For IS audience, eRoom should become the IS file location recommended to manage most categories of a working document;

- i. Limit as much as possible the number of eRoom for a same team;
- ii. Limit files level to five folders;
- iii. Limit number of folders at a same level to 15;
- iv. Leverage standard file structure, when defined for a team;
- v. Ensure through KPI monitoring that the new guidelines are followed by the organization;
- vi. Enlarge as much as possible the audience, except for security/confidentiality reason.

7.8.5.3 Overall file structure

In order for a file structures to be more intuitive, it was suggested to follow the same overall structure for all *IS* teams:



First layer = Team

Second layer = Audience

Third layer = Category of files

Figure 7-9: Proposed file structure for IS

7.8.5.4 Team level file structure

Each team will have their local (France, North America) and global folders. The objective, as an international team, is to have minimum items throughout the years in the regional folders, and more in the international folder.

Since, everyone has the access to all folders, a file produced in France would be a good reference for the international entity, this file shall reside in the French folder and a link should be created in the international folder.

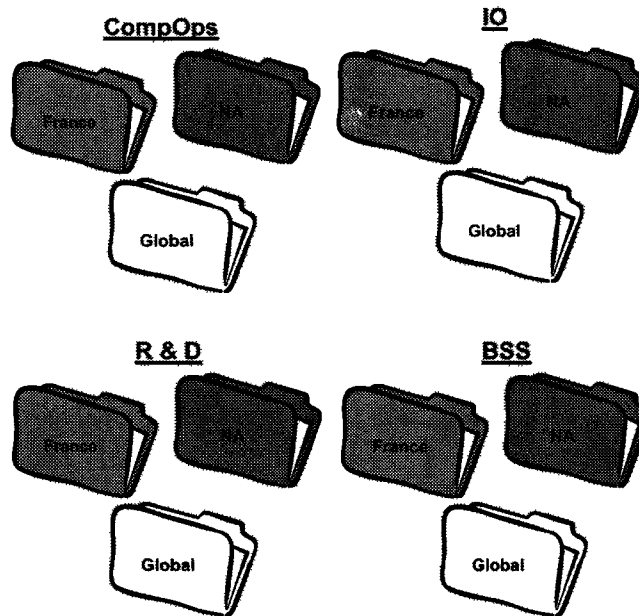


Figure 7-10: A possible way to structure eRoom at IS teams level

7.9 ISQV Intranet

The aim of this improvement plan was to develop an Intranet for *ISQV* activities presentation in the *IS* department. It involved ergonomics designing that help users navigate easily. To achieve this, various pages were produced to verify the final information, which was used to develop the *ISQV* Intranet pages. The planned to use the Intranet included a variety of ways such as:

- Communications tool
- Stable repository for publications (e.g., electronic versions of printed publications)
- Repository for information that changes frequently
- Search or query-based access to information
- An interface to multiple applications and information services

In view of the improvement plan, it followed a detailed analysis of *ISQV* activities, team member's views, from the initial stage to the launching of the Intranet. Several iterations were completed at each stage and some processes

within *Interligo* (the software used to develop that Intranet – recommended by the *IS* department) were simplified.

We verified that the Intranet pages ensure that the information content was an accurate representation of *ISQV* activities and supported its mission. The information were managed in accordance with *IS* web policies.

7.9.1 Introduction

In the recent past, the World Wide Web was being used as an important medium for accessing information and communication and it is thus necessary to make it more user-friendly. The utility of the Web has been an important catalyst in the growth of the electronic media. Today, we access it for all purposes in exploring the ways and means wherein one can retrieve the requisite information. We believe that the time taken for information retrieval process using the World Wide Web is an increasingly critical issue in obtaining the required information. Numerous studies investigated the effect of different contents representation of hypertext formats, structuring of information, on reading comprehension and search for a certain piece of information [56] [232]. Structured information helps to understand the information in a better way and to access directly with the help of relationships provided by keywords. In a broad sense, hypermedia increases comprehension [355].

7.9.2 User Friendly Intranet

Today, the companies with large Intranet structures, the creation of a user-friendly intranet, extranet structure can be a big challenge. The challenge is to better define the structure and categorize information, which can be helpful in getting the required piece of information in minimum possible time.

This is evident from experiments of [80] [258] [165] who measured different navigation characteristics, as measured by time spent for information retrieval. Structuring information helps one to understand the different pieces of information in a better way. Thus, comprehension also increases through the

enriched context that comes from sophisticated navigation support and supplemental relationships [355]. The research showed that it would be beneficial for the information-seeking process to have a clear organization of the information and try to convey it to the user. Thüring proposed some cognitive guidelines to represent better ways of organizing (grouping, categorizing, and clustering) to increase coherence and to reduce cognitive overload. These include:

- Equivalencies between information units are necessary according to their importance level: Headings could have the same size but larger than the size used for the next level subheading, and so on.
- Context of information units should be maintained: The overall context of actual node should be displayed together with its related nodes to help user see the overall space.
- Higher-order information should be employed: This enables users to identify important portions of the document and their relationships.
- Enable the user to visualize the structure of the document: A clear site map providing all the major pieces of information of the Web site can do this.

7.9.3 Intranet & Interligo Tool

Sanofi Pasteur used a tool “*Interligo*” integrated in the organization’s Intranet web page designing for which all web administrators were provided with training. These training sessions were helpful to understand the concept, functioning and utilization of the tool. This tool was easy and useful for non-technical web developer to create easily web pages. However, certain tool limitations did not allow the web designers to create different animations that were not included in this tool. It included a number of rules for page creation choice in selection of font, colors, images and graphs, etc.

The tool provided by *IS* Web team was used as a support with following features including:

- Producing a web snapshot of all content pages;

- Having a site map that shows relationships;
- Documenting web site content;
- Tracking changes to web sites between snapshots;
- Archives for ensuring the preservation of long term web content pages;
- Library facility to keep documents and images for use;
- Administration management and security to access the pages, etc.

IS Quality & Validation

Introduction

- Mission
- Organization
- Contact us

Quality Recommendations

- Quality System
- Quality documentation
- Available Trainings

Quality Improvements

- Audit Reports
- Objectives 2006
- Best Practices

Welcome

We are pleased to welcome you at our ISQV Intranet. Our team combines IS, Quality & Computer Validation together to promote a "Quality First" environment. Here, we provide you information about our quality services, recommendations and improvement practices for the IS department. ISQV need to involve everyone in the organization working together to obtain highest level of quality, internal customer satisfaction, business efficiency and regulatory compliance.

ISQV Services

ISQV services support business users projects, IS for various quality activities and IS technical services by implementing effective, and efficient quality practices like:

- Change Management
- Configuration Management
- Computer Validation
- Data Backup Management
- Regulatory Requirements (CFR Part 21, 21CFR, 21CFR, 21CFR, etc.)
- Validation

News

- **Training Session "Electronic Signature"** at Marcy in G Building 11/01/2005: Due to the large number of online registration for the fortnightly session at J Building J, a monthly session is added in G building. The next session is on 11/15/2005.
- **FDA Inspection at MLE in June 2005:** Overall assessment remained positive and all observations of the previous inspections and Warning Letter of the last year were raised.
- **CM Board Planning:** Please find the planning for CM board for the year 2006.

Useful Links

- ISQV Glossary
- FAQ
- Other IS Services
- IS Indicators

Figure 7-11: Home page of ISQV Intranet

All ISQV team members were involved in providing their suggestions in making links between the different web pages. There were three levels of web pages with an option of going backward or to the home page. Intranet was activated few days before my departure so I was unable to get the feedback from other IS teams about their perception of ISQV services presented on the Intranet.

7.10 Evaluation of QMS elements

All processes linked to CSV have a direct effect on quality. I found all the above presented improvement plans for CSV and file management as a source to evaluate the QMS elements. The primary objective of the evaluation was to assess the current situation and to propose the improvement plans for *IS* teams. An important but lengthy task was to gain a fair knowledge of QM for the pharmaceutical industry. At first, the work was supported by participating the *IS* quality manual which opened various channels to learn things and observe the QMS.

7.10.1 Top management

Awareness about quality is necessary for top management and in addition, encouragement of implementation of QM for all employees is also considered as the key task for top management. Whenever necessary a documentation system is proposed and applied in the organization, top management support remains the major drive for its implementation. When identified with *IS* teams, various points for file management practices were found presented in the table 7-10 to remove gaps. CSV and file management were identified for improvement and recommendations. The organization focused towards its business and QMS met the regulatory requirements, however, less importance was given to the deployment of best practices in terms of QM. Employees were provided with several tools for documentation without any proper guidelines and procedures. People were not aware of their proper usage (which tool for which type of documents, which type of structure to follow, when to archive a document, etc). Data were increasing at a rate of 50 % a year. Top management did not fully pursue these tools with appropriate training and how to use these tools for QMS. The reason can be explained as before many of the consultants were involved before audits and documented process for all important projects. Each project in-charge managed the relevant documentation and associated practices. Later, *ISQV* was created at the initiative of top management to manage and handle all quality activities related to *IS* activities. *ISQV* mission was to improve the QM and deploy best practices in *IS* department. With the introduction of *ISQV* team, top management was found more

committed to quality by introducing quality issues inside the IS but it was a start and it required many steps to be taken to make *ISQV* functional in a real sense. Thus, proper training to make the employees familiar with QMS was found important. Top management took a major initiative by creating an *ISQV* team with an objective to better focus on understanding the implementation of the QM system. More efforts were required by top management to involve employees in quality activities and audits. Thus, daily quality activities were not found coherent in all the teams. It was observed that employees were not aware of quality policies and among other factors, top management primary responsibility and commitment was to drive the vital role of QM in all the employees' routines. Thus, it can be stated: **Less the QMS is accompanied by top management, less the problem of the QM implementation is solved.**

7.10.2 Strategic quality planning

The purpose of strategic planning is to look for the coming challenges and to place the organization's likely efforts through concrete actions. The IS organization exercised with the help of a strategic quality planning offers a clear vision about QMS and regulatory authority audits need. Each year, millions of euros were spent in order to achieve full documented procedures for all important projects linked with the regulatory authority's audits. Each time, numerous teams and consultant were involved before a project was finally launched. The reason was to avoid any warnings from regulatory authorities that could harm the major business. The motive behind the *ISQV* team was to manage and capitalize all quality issues for the *IS* and to take advantage of the quality department for all *IS* teams. The reason for the creation of the *ISQV* was not fully described to all teams. It was first seen as a replacement of a consultant involved in quality projects to meet the requirements and necessary documentation in order to satisfy the regulatory authorities' requirements. Thus, teams were not approached to describe the organization's strategy. As an outcome, employees were not clear about the organization's strategy for quality and their allocated role remained ambiguous. For this purpose, more information was required to involve all *IS* teams in the quality loop. Strategic quality planning was given less priority and its explanation

and communication to all teams was not visible. In file management, it was observed that employees were not aware of any policies or procedures about these tools. No precise rules and guidelines were provided to take full advantage of these tools. Lack of communication remained limited thus leaving teams to move ahead without a shared vision of the strategic quality planning. This quality element has severe effects on QM implementation *i.e.* top management ability to create successful communication and promote the necessary changes is at the heart of successfully understanding the organization's quality strategy. In various workshops of *ISQV*, numerous actions were proposed to inform about the organization's strategic planning. These included printed instructions, increased training, distribution of training material, internal magazines, etc. all were intended as an aid in connection with the implementation of the organization's standards. Thus, it can be stated: **Less the QMS is accompanied by strategic quality policy, less the problem of the QM implementation is solved.**

7.10.3 Employee's training

Various consultants were involved in all the quality projects, so fewer employees had thorough quality knowledge inside the organization. In addition, the IS organization did not fully provide necessary quality training to various employees which were not involved in the regulatory authority audits. This can be seen as a barrier for many teams to carry out their activities with the quality department in an excellent way, thus, a quality integration effort was lacking to see all the teams working for QM. The organization used latest tools and technology to cope with the Information Technology (IT) challenges. Employees considered quality audits and quality issues handling as a sole responsibility of *ISQV* department or consultants involved in these audits. Without a constant focus on informed employees, successful implementation of QM was not possible. The organization was not fully using its resources as many of the employees were not aware of the optimal utilization of those tools. Employees were using the tools they liked instead of a standard procedure or guideline. People asked to limit the size of storage capacity of their documents that they thought forced them to sort out their documents (*i.e.* Outlook: there was a size limit for email). Team heads

were not aware of space storage allocated to their team and they were looking for better search tools. The existing file management tools were under used. It can be further translated that the organization was not accomplishing its quality goals because of a lack of effort in involving employees. In discussions with the team, it was observed that employees considered that quality department was producing only documents and increasing the burden in their routine duties. The change in perception needs a constant effort towards quality integration of all these teams in order to assimilate them in QMS. Training in QM for all employees was found necessary. When asked about the number of training, people said each employees attended more than 20 hours, however, training related to QM was extremely negligible which in turn create barriers to synergy in the organization's efforts to successfully implement QMS.

Involvement of employees in QM is linked to its application in daily activities. Teams were reluctant to use the quality directives in daily practices and considered it only for audit preparation. *ISQV* helped people in providing awareness about quality issues and it was a start. In 2004, only two employees were dedicated to it in France team. The next year in 2005, another employee was hired to support *ISQV* activities. *ISQV* initiated a program of quality leaders for all the IS team to share quality information in these teams. In the past, however, this practice was limited and remained less effective as feedback and motivation of other team was low. Thus, it can be stated: **Less the QMS is accompanied by employee's training, less the problem of the QM implementation is solved.**

7.10.4 Process Management

File management helped *IS* teams to better manage their documents on different tools. Various recommendations were put forward to improve the utilization of these tools. KPI were identified to archive the documents that were not accessed for a year. A team was recommended to define guidelines and help *IS* users to follow the structured process. These all led towards standardizing the file management process.

Soon after the finalization of CSV methodology, the validation process was carefully planned and various assistance forms were developed. These forms include the *ISQV* project evaluation form, IS validation plan form, IS installation qualification form, IS system release verification form, IS deviation form, and IS phase release form for operational qualification. The major objective of these template guidelines was to increase the standardization of the validation process.

The same approach was followed for the CM process in order to provide an improved assistance for all IS teams and remain in compliance with computerized system. The CM coordinator of *ISQV* who worked on managing the CM process under the guidance of the *ISQV* head, provided a number of training sessions on CM process for IS teams. A training session was held at team level and then another general training session for all IS teams. These sessions provided clarification on the CM process to familiarize IS teams in understanding the real notions of CM.

Before the development of the CSV and CM methodology, the effectiveness of these approaches remained limited. At that time, the utility and exploitation of processes were dependant on the consultant's involvement and quality teams handling of the audits for the project. Top management did not fully implement the standardized process management approach by considering all the projects aspects under single umbrella. Thus, it can be stated: **Less the QMS is accompanied by process management, less the problem of the QM implementation is solved.**

7.10.5 Communication-to-inform process

Continuous communication and interaction between *ISQV* quality department and IS teams was utmost to obtain the desired organizational quality goals. The intranet of *ISQV* was proposed and developed to enhance the quality efforts of the IS organization in order to promote its quality objectives. Various quality issues related to CSV, CM and regulatory audits were presented on the Intranet to provide a channel of communication inside the organization. Support from top management was found primordial to work on communication issues. The weaker aspect of communication and provision and sharing of information was

found among the primary reasons for developing the gap between QMS and organizational activities. When the file management project was launched, it was meant to reduce incertitude about rules and regulations for *IS* employees. At that time, only five people were aware of the record retention policy. This led to an environment of incertitude among employees about the organization's policies. The atmosphere of incertitude can be minimized with the help of increasing a culture of awareness. *ISQV* then conducted various training sessions to explain the importance of QMS, FDA regulatory audits, CSV process explanation and CM process. The purpose of these training sessions was to communicate the importance and usage of quality information and to develop a dialogue with other *IS* teams. These training sessions and workshops were conducted to assist employees in understanding the quality notions and to participate in the QMS by playing their due roles in achieving the organization's goals. Workshops on quality issues shared and promoted quality information among all *IS* employees. The organization was found to be more involved in ensuring that all employees were sufficiently informed about critical issues concerning the organization, including their quality strategy and quality processes for QMS. The communication was considered as the foundation for QMS on which the whole building of QM is constructed. Thus, organizations can be transformed towards full implementation of QM if the factor of communication-to-inform process is truly involved. Without effective communication the *IS* organization was not able to advance towards successful implementation of QMS. Thus, it can be stated: **Less the QMS is accompanied by communication-to-inform process, less the problem of the QM implementation is solved.**

Thus if we summarize the above quality elements, it can be stated:

Less the QMS is accompanied by **quality elements**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **top management**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **strategic quality policy**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **personnel training**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **process management**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **communication-to-inform process**, less the problem of the QM implementation is solved.

7.11 Evaluation of QMS implementation phases

In fact, the implementation reflects the level of an organization's QM level.

7.11.1 Quality integration phase

As discussed earlier, quality integration is the step forward to conform to the organizational documented procedures by putting it in real contact with employees. The integration includes assimilation of quality practices that requires strong sponsorship from top management. In the case study organization, the organization successfully conducted the regulatory audits with the help of quality departments and associated consulting firms. The case study organization had taken the initiative to lead to improve its quality planning, at that time, the organization already experienced an existing QMS system to accommodate the new improvement plans with its existing ways of doing business. Nevertheless, people from other IS teams did not perceive the organizational approach in the

same way. So, naturally, the dedication and involvement to participate in the approach was lower because employees were not aware of any file management procedure issued by the company. The existing procedure was not implemented by IS teams which demonstrated that QM standard existed without quality integration of employees. In addition, the interaction between *ISQV* and other IS departments to clearly understand the quality message started a few months ago after the creation of the *ISQV* department. There were only two members in *ISQV* at the start and further recruitment was in process. So much of the *ISQV*'s time was utilized in audit preparation, the IS departmental policy review and finalization, etc. In the past, the audits were well supervised under the guidance of quality experts and consultants to cover all regulatory issues, however, the quality integration in terms of common vocabulary quality language, communication and information sharing for quality tasks and assimilation to perceive the applicable system were supported only at the time of audit preparation. Consultants were hired on an interim basis to assist the organization for regulatory requirements. In the IS department, no quality team, before *ISQV*, supported the quality integration activities on a permanent basis. Employees's training on quality issues to absorb quality vocabulary and system were not aptly applied. A well organized documented quality system existed and included all required documents and procedures for every audit.

During an interview for assessment of file management, an *Accenture* consultant said that a team head had asked him what is meant by file management and what the organization is looking for. His team was not working according to the quality policy about file management tools. This situation demonstrated that there was a lack of use of quality tools in daily practices in IS teams. The gap in integration of the quality system remained a barrier towards a responsible participation towards QM implementation in a broad spectrum. There was a need for continuous interaction between quality and IS teams to inform teams about QM. To be informed, there was a need of on-going training for all employees. The organization did regular measures for many years, including engaging a high number of consulting services to satisfy all the quality audits and requirements for projects, creation of several quality teams (industrial, IS, etc) in order to avoid non conformities and create specialized profile of quality teams. However, top

management was required to do more for employees in terms of quality integration that in the long the run provides durable and permanent support for the organization in terms of achieving quality goals of the organization. Thus, it can be stated: **Less the QMS quality integration phase accompanies a QM standard, less the problem of the QM implementation is solved.**

7.11.2 Quality daily use phase

Various documented quality procedures were used at the time of audit preparation and were not meant for daily use. During the file management project, a record retention policy was found in documentation. However, only five people were aware of the policy and as a result no implementation in daily use was visible. Thus, QM lacks daily practice utilization to observe and understand its importance and effect on the organization's objectives. The organization conducted various training sessions according to its business requirements, however, quality training sessions were not compulsory for all employees. It was compulsory for those people who were going to participate in an audit, to write a quality procedure, etc. Existing knowledge and learning from quality training sessions was, thus, limited in various departments. There was a constant need for workshops and training sessions to help employees better apply the QMS and utilization in daily use. The implementation of QM demonstrated that the organization's daily quality use phase was weaker than compared to the possible level due to existing quality tools in use. The organization used a special software "Documentum" which kept all quality procedures with different versions. An *IS* database analyst was asked if he used Documentum to consult the quality procedures. He said "no" because the software required training before he could use it. He usually asked the *ISQV* team to track his procedures from the software. The principal reasons of less usage of QM could be explained as a lack of awareness and knowledge to use the quality tools and system in place. It could also be explained by less support from top management to continue quality integration to extend the daily use of the existing quality practices. Thus, fewer results were visible in daily routines that are meant to support QM implementation. Absence or limited use of QM reduced the effectiveness of any well developed system. Thus,

it can be stated: **Less the QMS quality daily use phase accompanies a QM standard, less the problem of the QM implementation is solved.**

7.11.3 Quality evaluation phase

Like all multinational organizations, the organization regularly measured its annual sales, sales growth, profits, market share, and exports. These indicators remained key elements for the organization to work on improvement areas for business as a world class organization, like our first case study, all the above factors gradually increased and paved the way to improve the quality of products. The deployment of quality best practices for file management and improved QMS for organization were sought as the way that could be used by the organization to develop and implement appropriate actions in order to improve its strategic quality planning. The reason behind the case study, led by me, was part of an observation and evaluation of the existing QM practices in the case study organization. The organization remained willing to measure the difference between the actual performance and the desired goal to achieve conformance and improve the system. The evaluation was done with the help of discussions and workshops to measure the improvement margin for quality. Certain areas were identified through this phase to propose some recommendations and to improve the way things being done. The weaker areas identified during this phase were not only to improve organizational effectiveness and conformance to documented QM system but also to influence an organizational QM implementation. Thus, it can be stated: **Less the QMS evaluation phase accompanies a QM standard, less the problem of the QM implementation is solved.**

If we summarize the above quality phases, it can be stated:

Less the phases of **QMS implementation** accompanies a QM standard, less the problem of the QM implementation is solved.

Less the **QMS quality integration phase** accompanies a QM standard, less the problem of the QM implementation is solved.

Less the **QMS quality daily use phase** accompanies a QM standard, less the problem of the QM implementation is solved.

Less the **QMS evaluation phase** accompanies a QM standard, less the problem of the QM implementation is solved.

I remained with the case study organization as a support for *ISQV*, but my direct responsibilities did not include the development and implementation of the QMS and that is why it remained easy for me to carry out the role of an observer with some distance to access the QMS. In addition, I was also able to use multiple data gathering through informal discussions, quality workshops, trainings and observations to consolidate and refine research results for evaluation. With the help of the *ISQV* team, a privilege access to various useful pieces of information was given which in turn seemed very helpful in conducting this research. During a one year period stay in the case organization, I was able to create useful working relations with key members of the IS organization it, thus, opened various sources of information to improve research results and to assist readers in offering a clear understanding of the case study. One reason of selecting the case study was the quality department that is familiar to me. However, this industrial context was a challenge of being aware of the significant issues and problems associated with QM in a specific industrial context of the implementation phases.

7.12 Conclusion of the study

Without awareness of QM, no department can play its role to implement QM. The awareness of QMS requires the sponsors from all departments to participate in the overall approach. Once the awareness is provided and acquired by informed employees, there is need to continuously update to ensure that the

quality expectations of the departments are met. This step requires an evaluation on a regular basis, and then an action plan can be launched to work on all the process areas (it can be taken on a small scale depending on the resources available and the objective). To be informed, employees need training on a regular basis to support organizational QM for implementation. Training is indispensable in communicating the organizational strategy, and ways of performing work. To accomplish the implementation of QM and to maximize cooperation on quality goals, team motivation methods are to be taken into account.

Quality is vital for an organization's success in all areas and requires top management involvement. Awareness of QM is more than a set of practices, it is also a philosophy of cooperation between management and employees, working for a mutual objective. The ultimate goal is to keep the system in the best state to serve the customer the desired product. This can be accomplished when an organization can use ongoing training and communication to inform its employees. It is the job of top management to interpret the QM standard and prescribe the necessary parameters such as focus on people. Communication may guide and shape organizational quality activities if used in a way to inform people about QM activities.

QM requires awareness to be used and built into organizations. The arguments are interdependent in that QMS is necessary, but it cannot be achieved without its supporting factors such as a common quality vocabulary, an employee's suggestion system, constant exchange of information, everyday use of system and evaluation of a system for implementation of QMS. QMS introduced in several organizations often become unsuccessful and when composed of several heterogeneous segments seldom succeed in implementation of a QM. Top management must be committed to implementing QMS. Resources must be devoted and existing internal systems changed to support the fulfillment of QMS.

In this case study, various parts of the research study of the QM framework and its application in a grassroots practical situation were demonstrated. Due to time constraint, those improvement actions were planned for the organization from a business and quality standpoint. This case study was a way to observe the QM implementation in the pharmaceutical industry context and understand the

limitation of quality problems in an *IS* department. The initial period in the case study organization was spent in understanding what was going on in the *IS* organization. Then identification of improvement areas was done with actions to be implemented.

The study of implementation of QMS in another case study organization increases the validity of our study. Thus, increasing the possibilities of generalization based on two organizations rather than only one. We have provided some insight into which type of difficulties these case organizations were expected to have in a QM implementation process. Before these experiences, I had an opportunity to observe another industry experiencing quality problems with its QM implementation. In other words, our understanding and observation may involve many associated quality problems that are explained in these case studies. It offers us greater confidence in using our approach in other multinational industries. This analysis of quality elements in the pharmaceutical industry to implement QMS demonstrates that the industrial context is important to take into account and QM implementation is not an easy task. It is an on-going job that can articulate the organization's culture through participation of all the employees.

Like the first case study, this second case study contributes to an approach that answers the question concerning QM implementation for which *Sanofi Pasteur* was selected. From the presented details about the organization's existing QM, it was stated that the organization did not fully acquire and deploy the quality elements and implementation phases to achieve a full QMS. Like the first case study, the process of evaluation helped the organization to generate improvement plans in order to improve the existing quality elements and QM implementation. The *IS* top management agreed to back up the improvement plan in order to lead towards an improved implementation of QMS. Therefore, it can be concluded that the proposed study was sufficiently effective for the organization's QM elements and the QM implementation phases for regulatory audits in *IS* of an information system and served the organization in developing the improvement plans. Thus, it is stated that the understanding of QM implementation developed in this study is applicable to this organization. It is concluded that the top management played a significant role in the process of QM implementation especially in the quality integration and quality daily usage phase.

The CSV preparation was experienced with an IS team in how they were able to check the whole process flow and the required documentation with the *ISQV* team in fair details. Since the CSV and CM methodologies were proposed two months before my departure, it is possible that these kinds of development in QM implementation changes may occur in the future. However, it is also possible that certain elements of the QM implementation and utilization exert a stronger influence than those elements we considered, and those other elements led to an increase in the QM implementation. For example, while the employees were working on the file management project, they were not given a choice of selecting other tools other than those proposed options as these were decided by the *IS* top management.

In this case study, an effort was devoted in organizing the spectrum of file management through comparison of the selected tools (eRoom, shared folder and public folder) in order to recommend several actions. The importance of selecting each tool appropriate to the storage of files was also considered. We noted that the use of KPI (like last access date, last modified date, etc.) would result in an important indicator to accommodate some file management requirements and to reserve space in storage for this purpose. Additional detailed studies are needed to define the types of problems for which tools of various types could be useful for particular documentation. The ability to incorporate these recommendations is a step in the right direction, because it provides the features for both file management and retrieval for non specialists.

One can ask if this study for QM implementation can be used in other industries. We have presented two case studies. Until now, we tried to understand QM implementation in two different industries thus increasing the possibilities of generalization. The approach adopted in this case study was based on identifying QM implementation in weak areas and this then led towards improvement action plans. Now to develop the generalization, another case study was conducted in the automobile industry, this is presented in case study three.

8 Case Study 3 – Volvo Powertrain

8.1 Introduction

Two case studies were already discussed in chapter six and seven. The purpose of this chapter is to provide the third case study for understanding and observing the QMI process in industrial environment. The overall purpose of these three case studies was to provide relevant and practical information for the development of QMI model presented in chapter nine. In this chapter, we present an overview of the third industrial case study. Section 8.2 presents the research methodology adopted in this study. Section 8.3 describes the reason for conducting this study. Section 8.4 presents the introduction of the organization. Section 8.5 describes the organization of the *Volvo Powertrain*, the *Product Development department* functioning, the *Product Development Laboratory (PDL)* aim, objectives and description of its test centres. Section 8.6 identifies the maintenance department, its objectives and necessity. The organization of the maintenance department teams, their quality tools (Computerized Maintenance Management System- CMMS, Failure Mode and Effect and Cause Analysis – FMECA), maintenance types (corrective and preventive) used in the department are mentioned in this section. Section 8.7 identifies the key performance indicators used by the PDL department. Section 8.8 the evaluation of quality elements. The discussion on evaluation of QM implementation phases with maintenance management context is described in Section 8.9. Identification of an improvement plan of key elements is described in Section 8.10. The conclusion is presented in Section 8.11.

8.2 Methodology

The presented case study was conducted to observe QM implementation in the heavy automobile industry. This section provides the methodology for this case study and the PDL department details. Then the research strategy is presented.

8.2.1 Sampling

The heavy automobile industry in the Rhône Alps region (eastern border) near the south of France was selected for study due to its vital industrial position in the country. The case study involved the data collected for maintenance

department (corrective, preventive and maintenance store) working in the *PDL* (Product Development Laboratory). Twenty-six members of maintenance teams were involved and six members of ETO (Engine driveline & Testing Operations) with seven members of LDG (Laboratory Development Group) were participants in this study from the PDL department who were involved in different QM activities. The ETO and the LDG departments are presented in section 8.4. In this sample only three participants were female. This relative gender homogeneity was not unusual since most of the people working especially in maintenance and operation department are males in the industry. All members had been in the PDL for at least one year.

8.2.2 Case study process

The study was carried out in the maintenance department of a multinational automobile organization's site in France, Lyon, in 2006-2007. At first, I proposed to conduct a case study of the organization. After the approval of the *PDL*, the maintenance management was contacted to make available a research coordinator to help me for the study in their department. The operational maintenance manager was asked to provide a briefing as a general introduction of the maintenance department, maintenance activities, organization chart, difficulties the department were facing, etc. and then, I planned a quick guided tour of the PDL test centres with a maintenance team member to familiarize myself with the working environment, test bench major processes, role of different teams, etc. Different team members of the maintenance department told me about the PDL department (history, current QM implementation practices, overall business performance, organization's rules and regulation, etc). The maintenance operational and back office manager provided me with the necessary details of the maintenance department (PDL maintenance breakdown time, total production loss, number of repairs done, preventive maintenance done in the year, etc.) to give myself an idea about the existing situation of the maintenance department. I started learning the CMMS (Computerized Maintenance Management System) tool that contained all data about maintenance done for test centres. Details about CMMS and test centre are presented in section 8.5. I read reports on FMECA (Failure Modes Effects and

Criticality Analysis) approach already done and proposed for the future concerning the maintenance department. The FMECA was carried out to prioritize and eliminate potential failure of pieces of equipment selected after analyzing the CMMS tool. Details about the FMECA approach is presented in section 8.5. PDL departments functioning and interacting with maintenance department were observed throughout the period. Several actions were proposed to improve cooperation between these departments. The details are presented in section 8.9.5. I arranged meetings with all the maintenance team members to collect more information about their job nature, maintenance strategy they followed, problems faced during past year activities and suggestions to improve maintenance. I participated in a training session on industrial security to familiarize myself with safety and security requirements of the test benches in the PDL. Afterwards, some key areas for improvement were identified with the help of the maintenance manager, based on his observations during 2005-2007. In addition, maintenance data were used to point out weaker areas for improvements. A detailed discussion with the maintenance management was held in order to finalize the improvement plan. An example of the improvement plan for FMECA analysis is presented in section 8.5). This improvement plan consisted of a set of improvement plans to reduce maintenance time. In order to make the improvement plan more practical and applicable, the managers of operational and back office maintenance were constantly contacted, and some members of the LDG and the ETO were asked to be involved in its development. These people were selected because of their participation in different improvement plans *i.e.* all LDG members were either involved in improvement of existing solutions proposed to the PDL test centre, or training for the ETO department to help maintain/improve the test centre. The ETO members were selected to deploy solutions proposed by maintenance or the LDG department for test centres (examples are presented in section 8.9). All these people were used after viewing their participation role in maintenance solution improvements (refer to section 8.9 for examples).

8.2.3 Case study description

The basic goal of the case study was to offer an example in order to observe the QM elements and QM implementation in the industrial environment. This was found helpful to developing a model proposed in the chapter QM modeling. Like other the case studies, this case study organization was asked to support me in accessing and observing the organization's quality elements and the QM implementation process. In this way, I proposed to establish an improved action plan after identifying the weaker areas. If this proposed plan is accepted by the top management to implement it in their organization, it can be inferred that the observation for QM implementation for improvement are applicable for the PDL organization.

Through detailed discussion among us (the manager of the operational maintenance and myself), it was observed that the top management of the organization was focused on providing sufficient support for the case study to be conducted in the organization. This seemed to be an important step in advancing towards implementing QM. Therefore, top management commitment paved the way for me to acquire the necessary information to conduct the study, in addition, to approaching all the relevant people. Without this step, the study could not have been conducted in the organization.

Another important step was to understand the quality vocabulary and language used in the PDL. The objective was to attain a reasonable understanding about the organization's vocabulary that helped later in promoting common quality terms in QM implementation. The evaluation of the quality elements and QM system observed daily activities in order to make improvement plans in these activities. Thus, the evaluation was considered supportive for the judgment and improvement of everyday activities. With the help of this evaluation step, which will be described in the detail below, weaker areas were identified for improvement.

The main aim of the improved action plans was to improve the QM implementation phases. At first, a list of identified weaker areas was bigger than

the final one. The list was further reduced to make all the action plans for improvements feasible due to time and resource constraints in the organization (including resources available, the impact of potential improvement on the organization's business and process activities). In addition, other departments of the PDL were also involved in order to better understand weaker areas and make the plan more robust. After brief discussions, the proposed improvement plan was approved by the maintenance management and an official acceptance was delivered to deploy further actions.

8.3 Reason for conducting this study

Although QMS is widely adopted by many organizations in their effort to increase organizational capabilities, the results of QMS have often been limited because of unreliable or inflexible equipment [346]. Therefore, it is important to include the maintenance management into the QMS. Maintenance is considered as a cause of heavy expenses and costly operation, often considered as a low status activity [299]. A well performed maintenance has a great potential on other quality operations [276]. Various studies conducted by academics and practitioners, have demonstrated that maintenance has a direct impact on productivity and quality [261] [357]. Within many large-scale plants, maintenance costs can account for as much as 40% of the operational budget [108].

The importance of the maintenance management had increased, due to its role in keeping and improving availability, performance efficiency, on-time deliveries, safety requirements, and total plant cost effectiveness [12] [236]. Maintenance is only one element, which contributes to effective operations during the life cycle of an item of equipment [256].

Our focus was to provide a set of actions to improve maintenance management. This could result in reducing failure rate and time. The performance of perceived maintenance depends on the perspective applied: the finance department considers it in terms of costs, top management in terms of budget performance, engineer in terms of applied techniques, and test operation in terms of equipment availability and responsiveness for all types of desired tests.

8.4 An introduction to the organization

This case study was conducted in the *Volvo AB*, which remained the world number two in heavy duty engine and number one in Europe in 2007. The working site where I did my industrial research was in Lyon in the Rhône Alps region (eastern border of France) near the south of France. The Group Volvo is divided into eight business areas (BA). The truck pole with three brands Volvo, Renault and Mack, represented the main activity of the group with more than 35000 employees, with 70 % of the group sales, in 2006. The vehicle range of Volvo and Mack Trucks (heavy duty vehicles) was different from Renault Trucks (light, medium and heavy vehicles). The Group Volvo was divided into five business units (BU). Each BA was linked to a number of BU that supplied components and services to support these business areas internationally. This organizational configuration allowed BA to work closely with their customers and efficiently utilize group-wide resources. The organization of the Group Volvo in June 2007 is presented in the *Figure 8-1*.

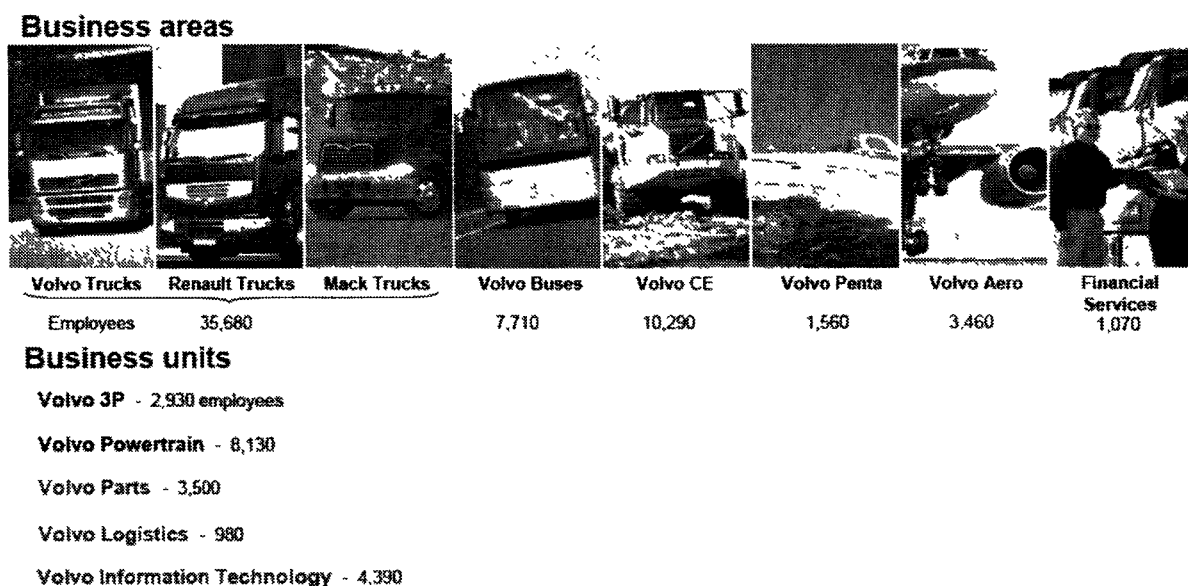


Figure 8-1: Organization of Group Volvo AB in June 2007

The task of the BU was to develop and supply components, services and support for the relevant BA. The major business units were *Volvo Powertrain*, *Volvo IT*, *Volvo Parts* and *Volvo 3P* (refer to *Figure 8-1*). I was attached to *Renault Trucks* (BA) and *Volvo Powertrain* (BU) which had four major teams:

Lyon in France; Gothenburg in Sweden; Hagerstown in the United States and Curitiba in Brazil *Volvo Powertrain* structure is mentioned in appendix 3.2. I worked in *Volvo Powertrain* that has common engine platforms to satisfy the latest environmental requirements, a research and development program, an efficient production and a supplier structure. Some details about Volvo Powertrain are presented in appendix 3.1. I worked in the Product Development Department (PDL).

8.4.1 Product Development Laboratory (PDL)

The PDL was responsible for coordinating engine test methods, planning and equipment for all development sites. The major objectives of the PDL were the following:

- To develop and provide standard testing services at the lowest cost and within deadlines;
- To apply the latest evaluation techniques (engine and driveline test, etc) in order to obtain valid test results efficiently and at the lowest cost;
- To design, develop, build and maintain high quality infrastructures and test cells;
- To plan, prepare and perform tests (mechanical, performance and specific) for engines (3, 5, 7, 9, 11, 13 and 16 l), transmissions and axles.

The PDL employed 145 employees in the Lyon site and was composed of four departments.

The **maintenance** department was responsible for the permanent functioning of the pieces of equipment, test centres and maintenance. Details about the maintenance department are described in the next section.

The **Laboratories Development Group (LDG)** department was responsible for defining, evolution, and implementing new solutions for tests to run, be validated and for post-treatment of test to be carried out. Security and

environmental standards were also the responsibility, at the time, of designing the new test centre.

The **Engine & driveline Testing Operation (ETO)** department was responsible to carrying out the tests and managing operation results. All operators in the operation control room were from the ETO.

The **Prototype Order to Delivery (POD)** department planned and prepared test schedules (timetables, test centre locations, types of test, components requirement, etc.).

The organization chart of the PDL in June 2007 is presented in *Figure 8-2*.

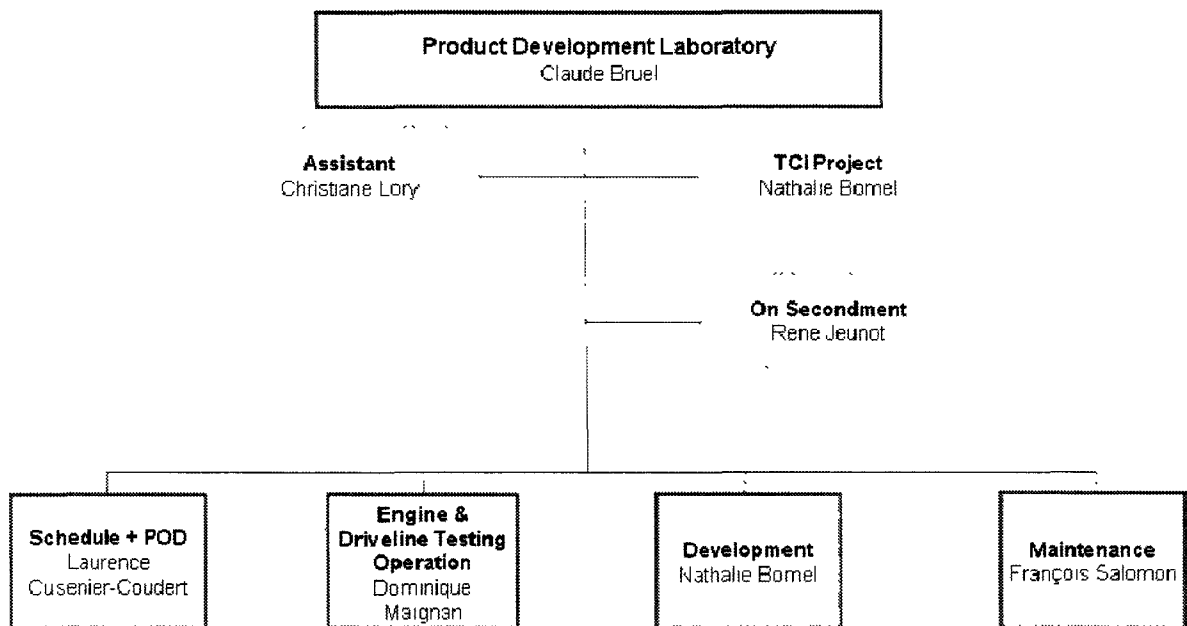


Figure 8-2: Organization of Product Development Laboratory France in June 2007

8.4.2 PDL test centres

Three major types of engine test centres were available in the *Volvo Powertrain* engine laboratories. Other specific test cells were used to study particular environmental conditions or to focus on special internal or external components of the engines. Some of them were planned to be closed in the coming

year after taking into account their specificity into new test centres. The description of a test centre is presented in appendix 3.5.

8.4.2.1 Durability test centres

These test centres were designed to run the basic and durable tests for more than 500 hours (up to 2000 hours) with only few short break intervals to control the wear and tear of the engine's components and to change the oil. As the durability of some components was tested, the probability of engine break down was quite high. The designing of these centres was especially made to ensure the safety of the testing operation team members who were responsible to conduct the tests. Usually, the basic required measurements were collected which included the engine's pressure, temperature safety limitation parameters and vibration in those types of tests. In addition, other complicated tests were performed such as thermal ageing, heat balance or vibration mapping of the engine. In Lyon, there were 10 durability test centres. The cost associated with one day's breakdown of a durability test centre was about 2904 euros. The test centre break down was the change from an "operable" state to an "un-operable" state during the tests.

8.4.2.2 Performance test centres

These test centres were designed to run short tests, usually less than an hour, with an accuracy of the load control system, of the temperature regulations and of the measurements. Gas emissions and performance of the engine were measured and all the sensors and gas analyzers required by the *Volvo Powertrain* for the development of the new engines were available in these test centres. These centres were used for official certification of engines before starting mass production. The *Volvo Powertrain* performance test centres were divided into different types depending on their exhaust gas dilution equipment. The European standards allowed to perform so called raw measurements (directly sampled from the exhaust pipe) of the pollutants. This is in contrast to US standards that impose the use of a CVS (Constant Volume Sampler) which diluted all the exhaust gases before sampling for analysis. In Lyon, only one test centre allowed the performing of US standard testing, the European test was conducted in the Hagerstown Laboratory. In Lyon, there were 12 performance test centres. The cost associated with one day of breakdown of a performance test centre was about 3340 euros.

8.4.2.3 Specific test centres

These test centres were designed to run specific tests, to control and verify particular characteristics of engines (acoustics, carburettor, mono cylinder, etc.). In Lyon, there were five specific test centres where a large range of tests were performed.

8.4.2.4 Common installations for all test centres

All test centres were located in two buildings (wings). Certain installations were used to serve all test centres, *i.e.* to supply energy and liquids (treated water and chilled water at a controlled temperature, fuel and oil supply (gasoline, kerosene, etc), main pumps to maintain pressure of three bars in all circuits, engine oils and antifreeze liquid, etc. A gas cylinder room was located in each wing containing gases for all test centres. The compressed air was supplied by the nearby site and was distributed to all the test centres.

8.4.2.5 Infrastructure and equipment in test centres

The size of the test centres varies for different test centres (the smallest was about 12 square meters and the biggest was about 50 square meters). All the pieces of equipment were installed around the engine to capture readings of the engine, which kept the central position in test centre. All measuring equipments were connected with the engine. Each test centre had a cockpit or operation room with a big glass window that allowed the operator to see inside the test centre. The central computerized system and other equipment measurements were controlled from the operation room. The basement contained the regulating and supply circuits.

The engine was rotated with the help of a dynamometer (generator). Other measuring equipments included exhaust emission gas measuring equipment, smoke meter, fuel consumption and regulation meters, engine safety measures equipment, double extraction ventilation system (from roof and basement to avoid a temperature of more than 50°C anywhere in the test centre). Pollution Gas measuring equipments allowed measuring of the concentration of hydrocarbons, nitrogen oxides, carbon monoxide and carbon dioxide in exhaust gases. An NH₃ Analyzer was used to analyze the concentration of ammonia in the exhaust gases. The Micro Tunnel measured the presence of gas particles in these exhaust gases

with the help of a filter. In addition, various other equipments for pressures and temperatures were also mounted on the engine at various points to measure different readings for the test.

8.4.2.6 Control room monitoring system

In the control room, the central monitoring computer was used to conduct the test, to communicate with various equipments and the engine, and the network application servers. The system was used to manage all types of tests: full load test (with maximum torque over speed range), test sequence (different speeds - higher and idle speed), etc. All test measurements were saved at various desired points including filtration of signals and calculations. Two types of softwares were used for monitoring the tests: Morphée software (made by D2T company) for all the test centres which were constructed after 2000 and Puma software (made by AVL company) for those test centres which were constructed before 2000. In the control room, a screen “Magelis” was available that allowed to control the test centre parameters (in fluids, ventilation, regulations, generator, etc). A computer “Osiris” was available in all the test centres that acquired real time data frequencies from different combustion measurements. Another computer was used to transform all measurements and data into the required format for manipulation of results of all these tests.

8.5 Maintenance department

The major objective of the maintenance department was to assure the maximum operational availability and quality of testing equipments. The maintenance policy was applied to reduce the maintenance cost involved with minimum possible production loss time. Responsibilities of the maintenance department were:

- to conduct preventive and corrective maintenance operations of all the test equipments and means of the PDL engine test centre;
- to assure the smooth supply (stock control, quality follow-up, etc.) and take delivery of all the products and parts, necessary to test activities, to maintain and the instrumentation;

- to coordinate with other PDL teams for improvement in services;
- to conduct standard instrumentation and adaptations of standard test equipments.

The maintenance department was created in November 2004 at the time of the reorganization of its various functions that were working separately in different teams before. The organization flowchart of maintenance department is presented in *Figure 8-3*. My role is indicated under the role of quality maintenance in this organization chart. I worked with all members of the maintenance team to complete several improvement actions mentioned in section 8.10.

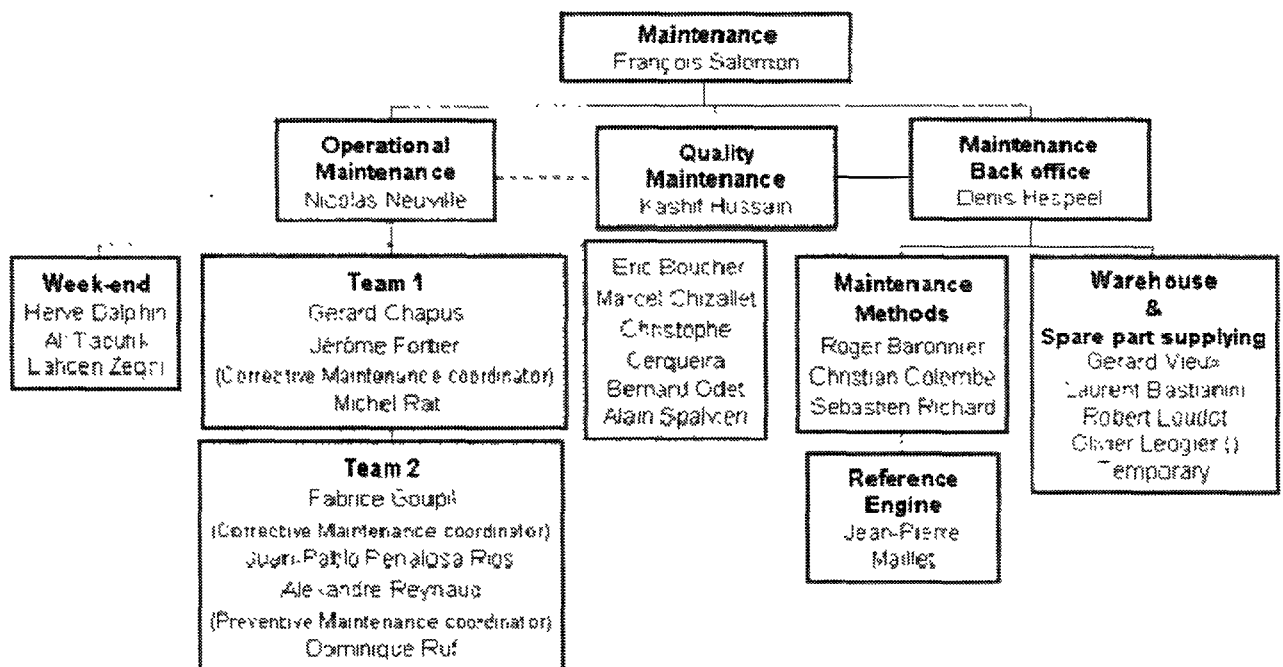


Figure 8-3: Organization flowchart of maintenance team in June 2007

8.5.1 Why maintenance is required

A failure in equipment not only results in loss of productivity, but also in a loss of timely services to customers, and may even lead to safety and environmental problems that destroy the company's image [13]. This can have a negative influence on customers who go elsewhere for their required services. Any production loss (if a test centre is unable to continue its operation) due to an

unplanned stoppage cannot be recovered without additional costs being incurred, e.g. overtime costs.

Maintenance objective: The objective of maintenance is to maximize the performance of equipment by ensuring that, items of equipment function regularly and efficiently, by attempting to prevent breakdowns or failures, and by minimizing the losses incurred by breakdowns or failures [256].

Maintenance was considered as a support function for all PDL departments. The PDL maintenance department used a CMMS (Computerized Maintenance Management System) to store all maintenance activities. The next paragraph provided some details about the CMMS.

8.5.2 Computerized Maintenance Management System (CMMS)

CMMS allows to track, estimate, schedule and control plant maintenance data, repair activities, etc. in a detailed level [256]. CMMS allowed handling a number of maintenance activities are the following:

- It offers a review of a number of elements (what work has been done, by whom, time taken to repair, quality of job done, spare parts used, etc).
- Assignment of jobs that can be handled to manage the workload.
- CMMS reports can indicate the levels of downtime with minor details.
- Control of spares modules is part of modern CMMS packages that can help to manage inventory and stock problems.
- Participation and expertise of maintenance team for specialized job can be seen which can further demonstrate maintenance personnel skills on different equipments.
- Equipments breakdown just after corrective maintenance or before preventative maintenance can be easily verified.

The method of requesting work (work orders) from the maintenance department was formalized with the help of a CMMS namely *Coswin 5i*. The maintenance department was responsible for this application in terms of organization and administration. It used *Coswin 5i* until 2006. All work orders or maintenance requests were entered in *Coswin 5i*. Each request (work order) was identified by a self-generated number by the system. The request included detail of the breakdown, associated equipment, and the test centre and nature of the failure (urgent – unable to run the test; less urgent – able to run the test but unable to fully utilize the functions of concerned equipment). *Coswin 5i* assisted the maintenance department to plan a work order according to the available resources and define the priority. It was found equally important to have a feedback on actual performance in terms of notification of completion and actual time consumed, by the maintenance team. This was incorporated in the work-request system. Until 2006, *Coswin 5i* was used by the corrective maintenance team only to exploit the data for calculating maintenance time for breakdown activities in the PDL.

The PDL management decided to upgrade the CMMS from *Coswin 5i* to *Coswin 7i*. Major reasons included difficulties in using several modules, availability of fewer functions, lack of control to verify accurate production loss and breakdown time, etc. A new project was launched to upgrade the CMMS version. The simplified process of CMMS (*Coswin 7i*) is explained in *Figure 8-4* presented below. The explanation of all processes of *Coswin 7i* is presented in appendix 3.6.

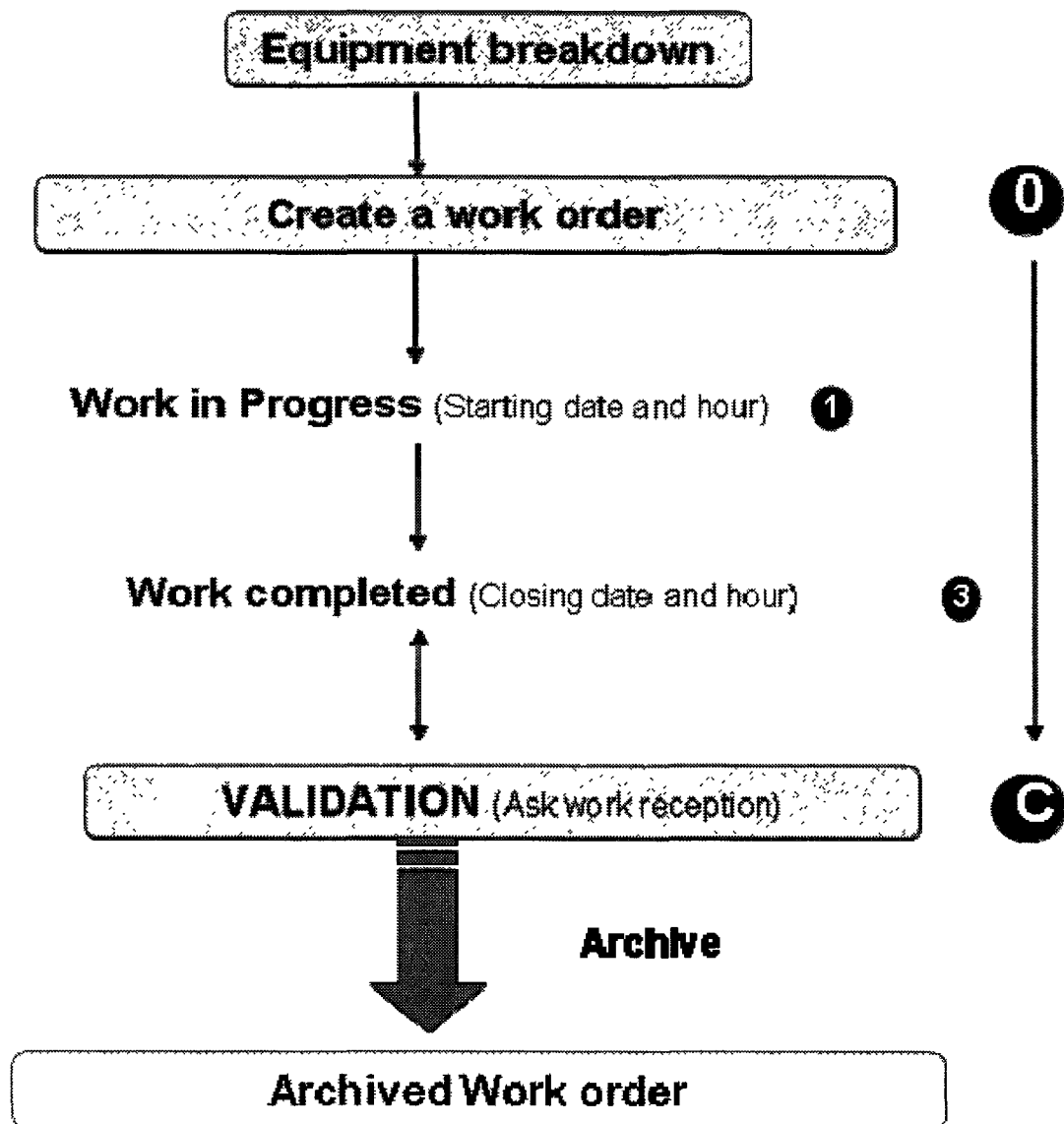


Figure 8-4 : Working of Coswin 7i in PDL departments

The components described here were appropriate for various types or levels of maintenance work including preventive, corrective, autonomous maintenance, spare parts availability, etc.

Status (0) Work Order Created: A request generated that asked the maintenance department to do a job. It identified problem description, nature of request, other necessary information to accomplish the required task.

Order of Priority: It was used to determine which work order had precedence. Since the maintenance department had limited resources available at any given time, the order of priority was done according to the PDL requirements

(type of test, test centre, equipment, etc.) in a formal (added in the Coswin dashboard - the priority test centres) or informal way (explained in the daily morning meeting - the priority test centres).

Work order already existed in the Coswin dashboard: All work orders in the backlog were mentioned in the Coswin dashboard of work orders that were yet to be done.

Status (1) Work Order received: Once a request work order generated by other departments was received by the maintenance department, the status was changed as “received and in progress” by the maintenance department. It identified the work order in progress from those which were not yet started for maintenance.

Status (2) Non-availability of spare parts: Various work orders performed by maintenance department involved the use of spare parts. In the case of non-availability of those spare parts, the work order was given a status “waiting for spare parts”. The aim was to inform all concerned people or users about the absence of the required spare parts.

Status (1) Reception of spare parts: After reception of spare parts from the supplier, the maintenance store changed the status from waiting for spare parts to “spare part available” status. This was to inform the corrective maintenance team about the availability of spare parts.

Status (3) Work Order done/maintained: Once a request work order generated by other departments was successfully completed by the maintenance department, the status was changed as “completed or done” by the maintenance department. It identified work order done and allowed department, which had made requests, to verify the quality and effectiveness of the repair done.

Status (C) Maintenance work accepted: Once a requested work order provided the satisfactory results after verification by the request generated department, the requesting department changed the work order status to “maintenance work done accepted” status. This was done after successful maintenance repair.

Status (4) Maintenance work rejected: Once a requested work order provided the unsatisfactory results after verification by the request generated department, the requesting department changed the work order status to “maintenance work done rejected” status. It was done after maintenance repair producing un-successful results that were not able to conduct the desired test. In that case, maintenance team worked again to repair and propose a viable solution. However, if the solution was rejected after a week, the maintenance team did not consider it unless a new work order was issued.

Status (D) Work order not completed: In the case where the work order information was found incomplete from any PDL department, the work order was given the status work order information “not completed”. The purpose was to alert the teams to appropriately complete the work order information.

Status (H) Work order verified and ready for archive: All work orders were required to be successfully completed by maintenance and accepted by the requesting department. Afterwards, a final verification by the responsible of the requesting department was done to assure the final verification of the associated production loss. Then it was given the status “work order verified and ready for archive”. The purpose was to alert the CMMS project in charge teams to archive those required work orders.

8.5.3 Failure Modes Effects and Criticality Analysis (FMECA)

The FMECA method was first developed by the U.S. Military in early 1950's when the technique was used in flight control system design and development (AMC pamphlet, 1976). In the industry, the FMECA technique (Ford Motor Company, 1988; US Military Standard, 1983) is a widely used method in the industry and considered as an effective and user friendly tool to identify, prioritize and eliminate potential failures that can affect the performance of a process or a product [34]. Then European countries used FMECA in the 1970's in the automobile and nuclear industries. For the automobile industry, ISO 9000 standard recommended that FMECA and other techniques be deployed. In 1993, the *Automotive Industry Group Action* and the *American Society for Quality*

Control defined the FMECA standards, which provided the general principles for the automotive industry.

The objective of the FMECA method is to resolve potential problems in a system before they occur. This can be done by the identification of the possible failures. Here, we break down any system or process into various sub-system components that defines its fundamental elements. Then a study to detect all possible potential failure modes and effects on the system is carried out. Action plans to avoid the failures, and/or mitigate the effects of the failures on the system are analyzed. A critical item list is identified (the probability, severity and detection of each failure modes occurrence). Then combining all the failure modes according to their importance gives the Risk Priority Number (RPN) [34].

The PDL management decided to use the FMECA method to reduce failure mode for equipments used in test centres concerning maintenance activities in 2005. A panel of experts (*i.e.* maintenance, LDG, ETO - which was made up of a large number of people to reduce the bias of individual opinions) was set up to apply the FMECA method. A formal view of the FMECA study is presented with an example of the fuel consumption meter in *Table 8-1*.

System	FEV- Fuel Consumption meter
Sub-system	Fuel conditioning
Function of sub-system	Pressure and temperature control of the fuel

Name of element / component	Function	Failure Mode	Possible Causes	Detection	Effects on sub-system	Effect on system
Liquid exchanger	To cool the fuel	Failure of cooling functioning	Clogging of the exchanger	Temperature regulation failure	Instability	None

ID (Index of Detection)	IP (Index of probability /occurrence)	IS (Index of severity)	RPN (Risk Priority Number)	Action Plan	Action Plan Number
2	2	2	8	Autonomous maintenance	FEV-CC-02

Table 8-1: Analysis of different failure modes for a sub-system

The resulting number for ID, IP and IS were calculated from the tables below which were used in the *Volvo Powertrain* for defining the FMECA criteria (probability, severity and detection). TIC was the breakdown time for a test centre.

Ranking	Severity (=IS)
1	TIC < 15 minutes
2	15 minutes < TIC < 2h
3	2h < TIC < 6h
4	6h < TIC < 24h
5	TIC > 24h
6	Security risk for personnel and equipments

Table 8-2: Ranking for severity

Ranking	Probability (=IP)
1	Less then one defect / year
2	1 defect every six month
3	1 defect every three months
4	1 defect every month
5	More than 1 defect every week

Table 8-3: Ranking for probability/occurrence

Note	Detection (=ID)
1	Possible to detect before test
2	Possible to detect during the test
3	Detection while analyzing the test results
4	Detection while doing preventive maintenance
5	Impossible to detect

Table 8-4: Ranking for detection

The resulting RPN was the multiplication of the above criteria (severity, probability and detection). The higher the RPN number was, the more critical the

system would be in terms of the failure mode. The actions plans to reduce the failure mode were diverse in nature including corrective, preventive, development of new equipments, trouble shooting, etc.

An example for FMECA approach applied is presented in *Figure 8-5* below.

Maintenance																
PI-14 : Application: Data Manager (Improve interface, clean database)																
Action description Equipment : Computer system System : Morphee Sub-system : test and configuration files Domain : LDG Start : W631 End : W652 <u>Action description</u> Clean and update the test and configuration files by naming to optimize the database. Modify the interface to facilitate the utilization for operators.																
Impacts attendus NRP : 72 + 60 <u>Existing Situation</u> Degradation of the database, load of useless files which prevent test running <u>Target Situation</u> Database readable, optimized and updated.																
Key performance indicators Key Performance Indicator • Repair & maintenance time (Increase the availability of test centers)																
Volvo Powertrain Lyon Product Development Laboratory																
Team Members FMECA Team Responsible : K. Hussain <u>Contributors</u> • LDG (Laboratory Development Group) • Corrective Maintenance • ETO (Engine & driveline Testing Operations)																
Work Plan <table border="1"> <thead> <tr> <th>Major steps</th> <th>Start</th> <th>End</th> </tr> </thead> <tbody> <tr> <td>1. Search the naming rules (if already existing) or redefine (LDG & ETO) as well as more readable structure</td> <td>W630</td> <td>W636</td> </tr> <tr> <td>2. Develop the tool and present it to ETO team</td> <td>W637</td> <td>W639</td> </tr> <tr> <td>3. Implement the new interface for the engine database</td> <td></td> <td>W640</td> </tr> <tr> <td>4. Clean the data base (obsolete and useless files)</td> <td>W650</td> <td>W652</td> </tr> </tbody> </table>		Major steps	Start	End	1. Search the naming rules (if already existing) or redefine (LDG & ETO) as well as more readable structure	W630	W636	2. Develop the tool and present it to ETO team	W637	W639	3. Implement the new interface for the engine database		W640	4. Clean the data base (obsolete and useless files)	W650	W652
Major steps	Start	End														
1. Search the naming rules (if already existing) or redefine (LDG & ETO) as well as more readable structure	W630	W636														
2. Develop the tool and present it to ETO team	W637	W639														
3. Implement the new interface for the engine database		W640														
4. Clean the data base (obsolete and useless files)	W650	W652														
Implementation Indicator Indicator Tool implemented in test center/ database updated																
Page 1 																

Figure 8-5 : FMECA action plan for a computer system application

8.5.4 PDL maintenance teams

The PDL Maintenance department was divided into two major branches (operational and back-up office) with 26 people. These included operational and back office maintenance of all test centres and their equipments and material (hardware, software, measuring instruments, generators, etc.). All PDL teams used CMMS to seek assistance of maintenance department. Maintenance department consisted of experts of various activities (mechanical, electrical, instrument measure, computer system, calibration, etc.). The policy of maintenance

department was to increase multi-skill teams to deal with various types of repair activities.

Operational maintenance was divided into two types of activities that included corrective maintenance teams and weekend teams.

Back up office maintenance was divided into three types including preventive maintenance teams, maintenance store team, and contracting out or supplier management team.

8.5.4.1 Operational Maintenance

Operational maintenance was designed to make all the necessary repairs dominated by un-planned events and to maximize availability of equipment for test centres. Corrective maintenance was the response to breakdown or failures. Its strategy described what events (e.g. failure, passing of time, condition and resources) were initiated and what type of maintenance decision taken (choosing between replacement or repair after inspection). Maintenance teams worked under constant time pressure. In the PDL, operational maintenance was supported by two teams.

Corrective maintenance (repair activities): Two teams worked in the morning and evening shifts on alternate basis. There were seven team members in both teams to maintain all corrective activities. In addition, there were five team members in day timings (from 08h00-16h00) to provide them support. The team included a member to solve computer related problems, two concerning instrumentation, one for emission gas problems and one for corrective activities. The state of affairs in a corrective maintenance team was dominated by unplanned events (*i.e.* failure of equipments, mal-functioning of equipments, etc.) which prevented the ETO department to continue their operation. Failures of important equipment might delay long-planned activities.

Weekend team (Special team for weekend - ESFS): In 2005, a special team for the weekend was created for preventive maintenance activities. The major objective was to save time during the weekdays (Monday to Friday). Various activities which were planned by preventive maintenance before in the weekdays

did not allow the test centre to perform their actions. With the help of this team, various activities were shifted to the weekend, thus, allowed more time for the ETO to operate the tests in the test centres. In 2007, after the re-organization of the maintenance department, the ESFS was attached to the corrective maintenance team. Before, the team was considered as a part of preventive maintenance team. The team was then trained for repairing maintenance activities also.

8.5.4.2 Back office maintenance

Back office maintenance was designed to provide support for operational teams through preventive maintenance, and provision of spare-parts in the least possible time with minimum cost. Its activities were to improve equipments' running conditions, analyze repair activities done and aimed at eliminating failures and defects. It was supported by two types of activities.

Preventive maintenance (PM): In PM, major activities involved were with an aim to exchange equipments' parts on regular intervals: inspection, perform measurement and diagnosis, correction of minor abnormalities, in the reduction of maintenance costs and improvement of equipment reliability. PM can be described as “maintenance carried out at pre-determined intervals or corresponding to prescribed criteria and intended to reduce the probability of failure or performance degradation of an item” (British Standard, 1984), regular pre-described servicing carried out periodically to eliminate defects and failure (Tsuchiya, 1992). Whenever any equipment was purchased, the supplier provided the details of required preventive maintenance. In the *Volvo Powertrain*, PM was planned for three types of interval, *i.e.* annual (principal maintenance of 10 days including various tasks- cleaning of a test centre, calibration and maintenance of equipment, cleaning of ventilation system, backup of computer files, etc.), biannual (maintenance of 2 to 4 days according to the type of test centre and once a year, six month after an annual maintenance) and quarterly (maintenance of 1 to 2 days in performance test centres only each three and nine months after annual maintenance) basis. PM involved details of all test centres to be maintained in advance in order to plan any PM. The explanation of different types of PM is presented in the following *Figure 8-6*.

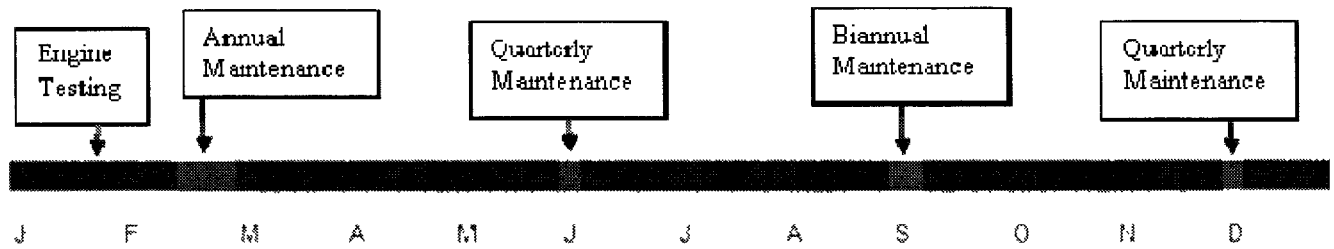


Figure 8-6: Different types of preventive maintenance in a year at the PDL test centre

An overview of PM plan for 2007 is presented in appendix 3.7.

Maintenance store: It was important to differentiate between maintenance store and general store. The administration of maintenance stores was considered as a part of the maintenance management because of the close relationship of this activity with the maintenance department. The role of the PDL maintenance store was vital. It was responsible for the provision of the required spare parts to maintain all equipments in the desired state (in both corrective and preventive maintenance). Time of provision of spare parts was important as absence of any critical spare part from the maintenance store readily increased the production loss time and maintenance cost. In addition, excessive inventory stock from the department requirements was a factor in the increase in inventory carrying cost.

Contracting out maintenance management (On site and off-site): A number of suppliers are involved for contracting out maintenance activities (including both preventive and corrective). In 2006, various suppliers were eliminated and replaced by a single supplier. This was to reduce the number of engaged parties in maintaining the equipment and to increase interaction with a single supplier. Advantages of supplier management include gain of time of diagnosis, fewer resources involved, fewer skills required for equipment under supplier maintenance management. Supplier's performance was observed with the help of indicators (cost involved, production loss, resources engaged, time taken for repair, etc). Contracting out maintenance management allowed organization to evaluate the economic consequences of decisions.

8.5.4.3 Prior to the maintenance department

Maintenance and development departments were started in December 2004, before this separation, both departments were working in the form of specialist groups. They were divided into four major teams *i.e.* instrumentation team, electrical services, mechanical services, and software development and testing services. Each team was responsible for the development and maintenance activities that fell into their specialty range. For example, the electrical team was responsible for all tasks (idea development, purchase recommendations, installation, verification, training, maintenance, decommissioning) of all electrical circuits, materials and equipments in the test centre. Afterwards, the PDL management decided to separate development and maintenance activities and formed a new department. The decision was not without consequences. Usually previous teams managed both activities in parallel. Their skills overlapped the development and maintenance activities. Some people were oriented towards development and others were towards maintenance activities. The transition phase was quick and people from all departments were informed from one to three months before the separation of activities into new departments. This phase was important for the new department because people were performing their job in a different way than before. The level of cooperation among different teams was no more the same.

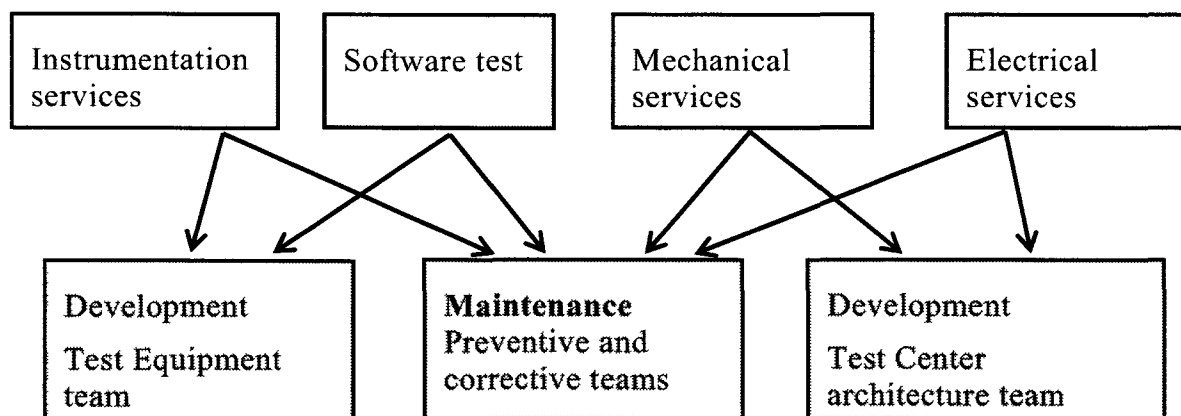


Figure 8-7: Functioning of different teams before the maintenance and the LDG department creation

In 2005-2006, three maintenance team members were retired from the department after completion of their job tenure. Due to the policy of reduction in staff members in all *Volvo Powertrain* departments, no new members were hired. The load of these jobs was distributed among other team members in order to continue the smooth activity in the maintenance department.

8.6 Key Performance indicators (KPI) used by the PDL department

Various KPI were used to represent the PDL test centres activity:

Rotation Rate (RR): Rate of rotation of test centre. It was calculated with the following formula: Number of rotation hours of test centre/total hours opening (test capacity).

Non-utilization: Test centre without any engine test.

Operational Problem: ETO department operation team was unable to conduct the test (absence of operators, etc)

Maintenance: Maintenance activities (either corrective or preventive).

Development: LDG activities in the test centre

Other: Unspecified part, which corresponded to various problems (failures of engine parts, quality test to verify test centre performance, etc.)

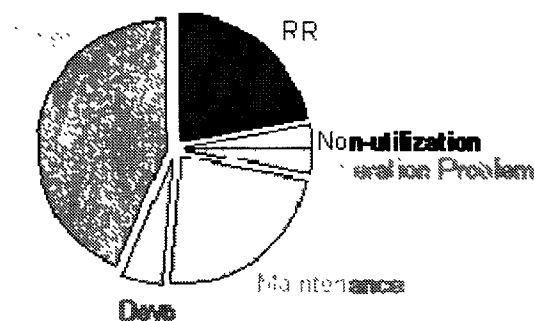


Figure 8-8: Several KPI for PDL test centre

The PDL maintenance worked to increase the RR (mean time between failures - MTBF) and to reduce the maintenance time (mean time to repair –

MTTR) associated to maintain the test centres. Each semester, a pareto chart diagram was used to determine the operational maintenance done for the PDL test centres. A pareto chart is used to graphically summarize and display the relative importance of the differences between groups of data (an example is presented in *Figure-33*). This allowed knowing the equipment that was responsible for high production loss. The total production loss time was calculated and then attributed to the concerned equipment. The pareto chart was helpful to focus on solving the most frequently occurring problems. It was to identify major equipments causing 80% of the problems. These were also called as the "vital few" causes most.

Operational manager provided me with the maintenance data for 2005. The Pareto chart for 2005 is presented in *Figure 8-9*. TM indicated the maintenance time for repair. The PP was the production loss time when the ETO department was unable to run the test. The first column explains the equipment code, the second column provided information about the number of work orders, the third column described production loss, TM percentage was calculated in terms of Pareto, and last column (comments) explained the equipment name.

CMMS Analysis for the year 2005 (Pareto chart)					
Equipments	# WO	TM	PP	% TM	Comments
BAIPOL	278.0	2827.0	3856.2	14	Emission bench
REGHUI	24.0	2911.2	2949.3	28	Regulation oil
ESSAI	117.0	1890.4	2603.4	37	IT tests
LOGICIEL	191.0	1731.2	2358.7	45	Softwares
ACOMES	163.0	1369.1	1585.9	52	Measurement parameters
BALCON	71.0	951.1	1415.6	57	Fuel Consumption meter
REGGO	97.0	882.9	1384.3	61	Fuel Regulation
GENEAVL	82.0	936.6	1165.8	65	Generator
UREE	19.0	210.8	1052.8	66	Urea
REGEAU	69.0	624.4	984.1	69	Water regulation
MICROTU	59.0	762.1	955.6	73	Particule Measurements
MELT	52.0	705.8	939.5	77	Electric Motor
DEPOUIL	86.0	492.6	864.5	79	IT tests result manipulation
REGMACHI	71.0	356.4	797.3	81	Regulation Machine
Total	1967	20637.9	29407.2		

TM= Maintenance time, PP= Production loss

Figure 8-9: Pareto chart for operational maintenance for 2005

The data were found helpful in exploring several factors involved in the breakdown. By viewing the data, we focused on various equipments which were

found important for maintenance management *i.e.* emission bench, software and test measurements, test result manipulation, fuel measurement meter, particle measurements.

8.7 Evaluation of quality elements for the QM implementation

The primary objective of the evaluation was to assess the current situation of maintenance management and to propose the improvement plans. Several key areas for improvements of the organization's QM implementation were identified. The weaknesses of the organization's QM implementation provided opportunities for the organization to improve its implementation process. Based on these weaknesses, the organization's targeted improvement areas, and the available resources, an improvement plan was formulated. The organization's maintenance director agreed that the department would implement this improvement plan in practice.

8.7.1 Top management

Top management was responsible to create the environment and structure that leads to high efficiency and effectiveness. For this purpose, top management was required to ensure the availability of all the necessary resources for their employees. Continuous efforts from top management were found necessary in order to engage the employees in quality. Deployment of tools like FMECA, improvement in CMMS system, and the availability of spare parts were linked with top management role. Top management took important initiative by introducing the quality tools in order to improve the maintenance management. However, tool provision was not the real motive behind utilization. Employees did not use CMMS system with all the details that were required to benefit from the system. Work orders were found with incomplete details. The lack of information in these work orders reduced the usefulness of the CMMS tool. The tool was merely used for maintenance management in earlier stages but was only used to store data. These employees were not well aware of the importance of these tools in earlier stages and top management was responsible for that. Top management put in place these quality tools for the department but a regular follow up and

employees' familiarization with these tools were done only by a single training on Coswin tool which was not sufficient. In addition, problems involved during this familiarization process and a viable solution provision remained on the shoulders of top management. There was a strong need of more maintenance activities (preventive, autonomous, spare parts availability, etc) for which employees need strong commitment from top management. Top management is the major driver to involve employees in pursuing the quality targets. Employees were required to have training on maintenance activities for which top management role was essential. The PDL department issued its first maintenance specification requirement in early 2007. It was better to create the document at the time of the creation of that department. A skill matrix chart was developed in 2006. When the new department was created, there was a need to help employees better understand the functioning of new departments and why it was necessary to work with the new organization. The integration phase in the new department required more efforts from top management to involve people in order to adapt themselves in the new organization structure. Thus, it can be stated: **Less the QMS is accompanied by top management, less the problem of the QM implementation is solved.**

8.7.2 Strategic quality planning

The change in organization from old to new departments was with an objective to define departmental parameters. However, there was a need to communicate more effectively the mission, and policy of the new department to all maintenance department employees, especially to the team members who were responsible for performing different maintenance activities in the test centres. The reason to separate both departments was not clear for some corrective team members. The creation of the applicable strategy was the critical and important task of management to achieve desired targets. Top management was responsible to explain the necessity of strategic decisions to all concerned employees. In this regard, top management could better explain the organization strategic planning to team members. From 2005-2007, the organization of maintenance was re-organized twice. The promotion of the strategy behind these changes was important to achieve the objective. Two newly hired members were found to be

more comfortable with the new structure as they were not integrated in the old structure. They were clearer about their tasks and activities than old members of corrective maintenance teams. This can be explained as the old members possessed experience in both maintenance and development that was essential to maintain the test centre. In the new structure, for all the development activities, they were advised to contact the development department. Management emphasized more on achieving a target without sharing the strategic planning that resulted in less involvement of employees. With the very first days, I observed that there was a need to communicate more about the strategy of the department. Whenever, there were various work orders to handle at the same time, maintenance department team prioritized the work order for repair. For this purpose, the maintenance team had to know the priority selected by the PDL department. This was sometimes, not known to the maintenance team. To do this, the dashboard of the maintenance department was used to display the priority of the test centre in the central office. The electronic display card was deployed that permanently indicated the strategy of the maintenance department. It was advised to communicate and to promote organizational strategic planning to all team members. In this way, people were engaged in the process of communication in the strategy in daily routines. Results were discussed with the departmental objectives on a daily basis. We consider the strategy as investment sources for the purpose of achieving goals. Thus, it can be stated: **Less the QMS is accompanied by strategic quality policy, less the problem of the QM implementation is solved.**

8.7.3 Employee's training

Depending on the role attributed to maintenance teams and their place in the maintenance skill matrix, maintenance team members tend to have diverse background and professional experience. Before the existence of the maintenance department, both departments (development and maintenance) were involved in problem resolution that later switched towards maintenance department responsibility. Corrective maintenance team members required several training sessions on equipments that were not provided before. The organization used quality tools to improve equipment reliability and reduce production loss time.

However, people were not fully aware of the usefulness of these tools and as a consequence were reluctant to use them in the required manner in daily routines. Old Coswin system 5i was not available with full details of repair. In order to know the details, one had to contact the team member who had performed the maintenance operation instead of looking directly in the CMMS. The lack of interest in writing in details was due to the lack of awareness of the importance of the information. In the new version of software *Coswin 7i*, awareness sessions were held in which it was made clear to all team members that their participation was extremely important in mentioning all repairing activities details. Otherwise, the new system will not be helpful for maintenance management activities. In daily meetings, all team members discussed in details about the progress of activity. The organization of the maintenance department was changed in December 2006 again with increased focus on multi-skilled teams. PM team members were asked to participate in corrective maintenance activities to improve their skills in breakdown maintenance. It was limited due to the ongoing preventive maintenance activities going on in parallel. However, during various delayed or cancelled preventive maintenance activities, the PM team members joined corrective maintenance activities. Teams were provided training on specific equipment. Moreover, all weekend employees were given training on basic corrective maintenance. Seventeen training actions were identified in the FMECA approach and deployed. Among the 17 training actions, nine were planned for the ETO department. Thus, it can be stated: **Less the QMS is accompanied by employee's training, less the problem of the QM implementation is solved.**

8.7.4 Process management

Engine test centres were constructed to develop and perform relevant tests in order to observe performance of different engine parts and the durability of several engine components. The functioning of equipments and instruments is highly important to measure engine tests. The maintenance department was engaged to maintain its functioning, thus, playing a critical role in all these tests. Increasing production loss demonstrated that the process was required to be reviewed to improve process management activities. The production loss and

number of work orders were reviewed in 2005-2007 in order to improve operational availability of the test centres. The organization calculated the process efficiency by identifying the number of hours the test centre had available for tests, number of hours maintenance was done, etc. However, such calculation had limited results unless people were not engaged in the QM awareness process (involvement in processes, usage of quality procedures and tools in everyday routines and propositions to improve the processes). Process management required sponsorship from all teams for which collaboration among LDG, exploitation and maintenance was required. A lack of collaboration resulted in a loose grip in the management process. QM usefulness was limited when I started work because employees were not effectively made aware of how to participate in the improvement process. During the FMECA approach deployment, it was found that preventive maintenance was not done for the computerized system that was among the higher production loss equipment. Computer specialists from the maintenance department and LDG department experts were engaged in providing the necessary PM plan that was later implemented in 2006-2007. Similarly, autonomous maintenance was done to improve the test centre run time. On average, ten work orders were blocked per month due to the lack of spare parts. There was a need to improve the stock available for the maintenance store. Five pieces of equipment were purchased with a number of spare parts identified in 2006. A list of critical spare parts was established. From 2006, people were engaged in identifying weaker areas for improvement with the help of FMECA, CMMS tool, suggestion system, etc (refer to section 8.5 and 8.9 for examples). We worked with PDL departments to make a collective effort for QMS improvement (refer to section 8.5 and 8.9 for examples). In 2007, a comprehensive study was done to observe detailed explanation of maintenance activities and its impact on test centre rotation. Three percent of production loss was reduced in 2007 despite the departure of four maintenance team members until 2007. A computer specialist helped the department in reducing the production loss by 10 % for computer software as compared to 2005. He was compensated with a small increase in salary by the operational manager. It was stated that the process management had improved in the year with the help of proposed action plans that were implemented. Details about improvement action plans are mentioned in the next

section. Thus, it can be stated: **Less the QMS is accompanied by process management, less the problem of the QM implementation is solved.**

8.7.5 Customer Focus

Customer focus was beyond the scope of the study as the author of this study was not involved with the organization's customers. However, if we considered the next process is the customer, then ETO requirements and collaboration was dealt in a way to improve the customer's expectation in running the test centre to perform the test in improved conditions. Both departments were contacted to cooperate on maintaining the test centre to meet the PDL objectives. Constant efforts were required to understand both the departments' requirements in terms of increasing operational time and reduction of maintenance time. ETO was involved with maintenance to a large extent in maintaining and operating the test centres after various efforts. ETO was contacted on a regular basis through various sources (FMECA, CMMS explanation, trainings on autonomous maintenance, communication, etc). *Coswin 7i* was used as a first contact with ETO teams to establish the existing problem. Reduction in production loss and quick service was not only important for the maintenance department but also vital for ETO to continue their activities. All problems concerning LDG were communicated on a regular basis to resolve work orders in the least possible time. A feedback from ETO was required in the new software (*Coswin 7i*) in order to evaluate the maintenance service provided to repair the equipment. Later on, a weekly and monthly report was sent to ETO department in order to know the production loss, time of maintenance, assistance for operators, etc. Nine training actions were identified for ETO to improve the equipment's reliability. Twenty equipment were identified as critical items to purchase for maintenance department and to keep in mechanical store. The aim was to keep the stock in advance in order to repair these identified equipment quickly. This was with an aim in increasing focus on customers' need. Thus, it can be stated: **Less the QMS is accompanied by customer focus, less the problem of the QM implementation is solved.**

8.7.6 Supplier Management

The issue was beyond the scope of the study as the author of this study was not involved with the organization's suppliers. However, if we considered the previous process is a supplier, then the LDG collaboration was considered as a way to communicate the client's requirements (ETO) which fell in the LDG activities that improved the services provided to the customer in running the test centre. LDG was contacted on a regular basis in terms of development issues of the test centres. Various combined work orders were handled with LDG with a dual objective. One was to improve coordination among both departments and the second was to improve the final solution proposed to ETO. Reduction in production loss and quick maintenance service was not possible without LDG cooperation. Various improvements in test centres were proposed to LDG to facilitate equipment maintenance and running of tests. A regular follow-up was done to evaluate the coordination. In FMECA project, 25 % of improvement actions were linked with LDG. It involved improvements in test centre facilities, training process, improved solutions for maintenance, etc. All these actions were achieved with the help of the LDG co-operation. A weekly and monthly meeting was arranged with LDG to increase collaboration and improve maintenance management for PDL test centres. Various solutions were proposed by LDG that were mentioned in the next section. Thus, it can be stated: **Less the QMS is accompanied by supplier management, less the problem of the QM implementation is solved.**

8.7.7 Communication-to-inform process

Several identified areas for improvement were communication-to-inform process among the different PDL departments. This communication process was considered vital for the successful quality maintenance management approach. The desired information of all relevant departments was found essential to be communicated in improvement actions. Before, less focus on communication was provided to the maintenance department that could be partially blamed for the production loss and reduced collaboration among departments. We focused on

communication to inform with other departments that included VIT, LDG, ETO and POD departments (refer to section 8.9.5 for examples). In 2006-2007, collaboration meetings among ETO and maintenance were almost triple as compared to 2005. LDG and maintenance collaboration meeting were doubled. VIT contact was established before all VIT actions. POD provision of test centre schedule was improved. All the improvement plans were basically the start of the aim to improve the communication of maintenance management inside the maintenance department and inside the PDL departments. Inside the maintenance department, it helped team members to increase participation after having a better perception of quality tools. Understanding the necessity and importance of the new organization in the maintenance department was done with in a communication-to-inform process. Quality tools were better used then before *i.e.* CMMS work orders were rarely unfilled by team members. Thirty two equipment were studied with the help of FMECA approach and more than 100 improvement actions were launched during 2005-2007. The “suggestion-box” system was introduced and suggestions were gathered from team members.

Collaboration among the PDL team was launched with constant communication to develop the mutual understanding of departmental goals in the PDL context. Mending these broken links of information helped the PDL maintenance teams in two ways:

- Reduction in production loss for those equipment which were higher in 2005 than 2007 and number of breakdowns;
- Support from other departments to foster maintenance management.

Inside the maintenance department, collaboration among different teams (corrective, preventive, instrument and maintenance store teams) was increased. The organization of maintenance was again improved in December 2006. All teams were engaged to provide maximum information about maintenance activities to each other. All maintenance results of different teams were shared in weekly meetings and discussed for deployment of actions plans. A network of equipment specialist members was communicated to PDL departments. These members were either from the LDG, Maintenance or ETO departments. These members were

selected from each department due to their in-depth knowledge about several equipments. The objective was to create contact among these members in case of an urgent need to solve a problem concerning the equipment. Thus, more information was provided to all PDL departments in order to meet the departmental objective. Thus, it can be stated: **Less the QMS is accompanied by communication-to-inform process, less the problem of the QM implementation is solved.**

Thus If we summarize the above quality elements, it can be stated:

Less the QMS is accompanied by **quality elements**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **top management**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **strategic quality policy**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **personnel training**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **process management**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **customer focus**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **supplier management**, less the problem of the QM implementation is solved.

Less the QMS is accompanied by **communication-to-inform process**, less the problem of the QM implementation is solved.

8.8 Evaluation of QMS implementation phases

The primary objective of the evaluation was to assess the implementation phases of QMS in maintenance management. It was helpful in finding key areas for improvement.

8.8.1 Quality Integration phase

The phase of quality integration was found weaker in this case study organization at the start due to change in the organization and due to fewer efforts in this phase in the early stages. The case study organization successfully conducted the ISO audits with the coordination of quality departments. The case study organization had taken the initiative to improve the development and maintenance services by separating both departments. However, once the old departments were formed into new departments and roles and responsibilities of team members were changed, it was important to manage all the changes caused in the transition phase. The phase of establishing the needs of new departments until they functioned effectively required constant communication of why the change was necessary to all the concerned employees. To integrate teams in implementing the QMS, more efforts from management were required as compared to the old organization. In addition, the interaction between maintenance and other departments took time to clearly understand the objective of new departments. In fact, PDL management proposed several tools like CMMS and FMECA to guide maintenance management in quality issues, however, quality integration in terms of common vocabulary language towards QMS, communication-to-inform process and information sharing for quality tasks and assimilation to perceive the applicable system was not the same for everybody in the department. Work orders of 2005 were found incomplete in the CMMS system by some members. It indicated that quality tools deployed in the department were not properly used by team members of PDL. Then a focus on the right utilization of CMMS was raised. It is stated that if the employees were well integrated before in using these tools, these types of problems could be avoided, or at least limited. Employee's training was required for better utilization of these quality tools that was not focused at the creation of the department. I had discussions with the PDL teams to observe the

real picture of QM implementation in the PDL department and the key points for improvements, presented in the next section, were accepted by the PDL maintenance management that might affect quality integration. Top management was willing to do more for employees in terms of integration that in long run provide durable and permanent support for the PDL maintenance.

A major step in quality integration was the responsibility and authority to coordinate common quality equipment vocabulary in the PDL departments. For this purpose the ETO department was provided with numerous information, explanations and procedures about equipment activities. The LDG department was asked to participate in various training sessions with an objective to deploy common quality vocabulary and for participation in the PDL objectives. The PDL maintenance management was seen in a quality approach to improve QMS implementation. Employees of maintenance were engaged and involved in participating quality maintenance activities and operational environment (training, collaboration and data provision for production loss and breakdown activities) with other PDL departments that were considered major actors in the provision of solutions. All the department team members were involved in participating this quality integration phase through deployment of improvement actions.

A monthly meeting was arranged by maintenance department to provide KPI (key performance indicator) for PDL department. This was shared among all PDL departments to provide all departments information about maintaining the PDL test centres. This was helpful for all PDL departments to visualize the test centre data in terms of production, stoppage for breakdown, reasons for breakdown, major causes, etc. As a result, all PDL departments agreed to work more on attaining the PDL objective. Common quality maintenance vocabulary was used extensively among ETO and maintenance departments through regular weekly meetings and exchange of data, breakdown problems discussion and feedback on solutions (refer to appendix 3.8 for an example). Thus, it can be stated: **Less the QMS quality integration phase accompanies a QM standard, less the problem of the QM implementation is solved.**

8.8.2 Quality daily use phase

There was no standardized document that described the PDL maintenance department's requirements in the PDL projects. Thus, in various projects, maintenance demands were considered in a heterogeneous way. No well identified maintenance demands were verified during the new projects. The maintenance department's considerations were taken partially at the individual requests of the team members. Thus, maintenance activities were adversely affected by such an approach (lack of corrective maintenance guidelines, absence of preventive maintenance instructions, missing or incomplete documents, etc). In December 2006, the maintenance management wrote the first generic draft defining the departmental requirements and specifications for all projects. Afterwards, the document was used at the time of launching new and on-going projects. After identification of various improvement areas, there was a need to constantly work on these issues. The organization conducted various training sessions accordingly for the PDL teams at the initiative of the maintenance department to better maintain PDL equipment. These sessions were done in order to cover the PDL maintenance management integration phase. There was a constant need for communication and training to help PDL teams better realize the quality approach of maintaining the equipment. Once the approach was clearly understood, there was a need to use it in daily routines. The evaluation resulted in the identification of several key areas for improvements, which were presented in section 8.9 and it demonstrated that the organization's daily quality use phase was weaker. That is why, at first, fewer activities were visible in practice in daily routines that were meant to support the QM implementation. Absence or limited use of QM reduced the effectiveness of any well developed system. CMMS was not used on a daily basis to provide full details by PDL maintenance and ETO teams. Both teams were engaged later to assure the proper utilization of the quality tool.

A constant focus on communication was done to continue collaboration among departments. Regular meetings were arranged to monitor implementation of actions in daily use. All autonomous maintenance activities were monitored that were prepared with the LDG department for the ETO department to use on a

regular basis. The ETO team was asked if they needed any further explanation about practice implementation. In addition, all procedures were fed into the CMMS, and the ETO interface was improved in such a way that a message was displayed on the day with the required autonomous maintenance actions details. This was helpful in using procedures on daily routine for all ETO teams.

CMMS was extensively used by all maintenance teams and the procedures for utilization were respected. Increased use of defined activities and respect of procedure demonstrated that people were taking into account these procedures in their routine activities. As a result, tracing information was easier for management and all team members by consulting the CMMS.

By the end of 2007, it was observed that team members were looking for innovation in their work. When the suggested system was introduced, team members proposed various ideas among which 10 were selected as immediate improvement opportunities. It was a sign of improvements in daily practices that were observed as a springboard to introduce improvements. All improvements that led to teams to think continuously were working as a catalyst for change towards improvements. Thus, it can be stated: **Less the QMS quality daily use phase accompanies a QM standard, less the problem of the QM implementation is solved.**

8.8.3 Quality system evaluation phase

Like the first two case study organizations, this organization regularly measured its annual sales, sales growth, profits, market share, and exports. These indicators remained key elements for the organization to work on improvement areas for business as a world class organization, like our first two case studies, all the above factors gradually increased and paved the way to improve the quality of products. The reason behind this case study was that part of the study of existing QM practices was to observe the implementation level of QMS. The organization remained willing to measure the difference between the actual performance and the desired goal to improve the system.

We started doing work by analyzing the existing situation to identify room for improvements. We took the help of departmental managers, team members about the way work was being done, CMMS database, problems encountered and weaker areas. This evaluation process was taken as an assessment to measure the difference between actual performance and the desired one. It should be considered as a permanent and a continuous process. The objective was the identification of improvements by provision of ways to ensure improved control of performance. Assessment of the QMS led to identify improvement areas and strategies adapted and adjustments according to requirements. Then the focus was to reduce weaker areas impacts and elimination of possible production loss by formulation of improvement actions. The reduction in 3 % of production loss demonstrated that the evaluation plan led to some sort of improvement. In addition, collaboration among different department was not possible without evaluating its need.

The evaluation paved the way to move towards continuous improvement. The process of evaluation turned around the collection of information and data on QM elements (people, process, customer, supplier, etc) and the development of improvement actions accordingly. All actions were communicated to maintenance teams in order to share, participate and work on improvements. Without evaluation, it was difficult to proceed for improvement. Thus, it can be stated: **Less the QMS evaluation phase accompanies a QM standard, less the problem of the QM implementation is solved.**

Thus, it can be further stated: **Less the phases of QMS implementation accompanies a QM standard, less the problem of the QM implementation is solved.**

If we summarize the above quality phases:

Less the phases of **QMS implementation** accompanies a QM standard, less the problem of the QM implementation is solved.

Less the **QMS quality integration phase** accompanies a QM standard, less the problem of the QM implementation is solved.

Less the **QMS quality daily use phase** accompanies a QM standard, less the problem of the QM implementation is solved.

Less the **QMS evaluation phase** accompanies a QM standard, less the problem of the QM implementation is solved.

8.9 Improvement plan of key elements

After viewing the data obtained from CMMS, discussions with maintenance teams, problems maintenance teams faced, difficulties in maintaining the equipment in operational conditions and weaker areas, I was able to identify several weaker areas for improvement. These include:

- **Steering the actions of FMECA to reduce equipment failure**
 - Continue working on the FMECA project to improve the reliability for the equipment of test centre.
- **Training**
 - Training for ETO departments.
 - Autonomous maintenance
 - Other training
 - Training for maintenance departments.
 - Training for weekend teams for repair activities.
- **Preventive Maintenance**

- More preventive maintenance was required on software testing equipment.
- **Standardized equipment**
 - All new installed equipment were highly recommended to be the same in different centers whenever possible to avoid different types of equipments.
- **Improvement of test centre equipment**
 - Improvement in the function of test centre equipment was necessary for some equipment. The development team was required to improve the function and design in order to facilitate maintenance and equipment functioning.
- **Collaboration of other departments**
 - All actions from *Volvo Information technology (VIT)* were required to plan in advance by the maintenance department before any modification / upgrading in the test centre.
 - Test solutions from the LDG department were required after informing the maintenance department before deployment in any test centre.
 - Preparation of autonomous maintenance and training for testing operation was necessary.
 - Modification in PM planning due to change in the schedule by POD was required to be communicated as soon as possible.
- **Spare Parts**
 - Investment on equipments' spare parts.
 - Spare parts list for 20 equipment.
 - 5S audit.

- Availability of spare parts in the maintenance store in advance was required to repair actively.
- **Documentation**
 - The documentation and maintenance guide was considered compulsory for all new projects and a place was required for all document of equipment.
- **CMMS**
 - CMMS (Computerized system management system) needed to be better used.
 - Upgrading of *Coswin 5i* to *Coswin 7i*
 - Training on *Coswin 7i*
 - Report development from the new version of *Coswin 7i*
 - Warranty and serial number of equipment
- **Suggestion system**
 - Involvement of employees by asking them for their suggestions for improvement in working environment.
- **Other actions for improvement**
 - Skill matrix chart, maintenance specification file, etc

8.9.1 Steering the project “FMECA” to improve equipment reliability

The FMECA methodology allowed the maintenance team to work on main hazard areas and was conducted from 2005 to March 2007. The whole process of the FMECA method was defined and 20 equipment were selected for analysis based on production loss and number of work order for repairs. I was assigned as a coordinator to continue all the improvement actions for this project. Steering this

project involved working with ETO, LDG and maintenance teams to implement action plans. In launching the FMECA approach, the first months were found to be difficult in terms of arranging meetings with the ETO and LDG teams to participate in this process. The major part was to communicate the importance of FMECA in a PDL context because ETO and LDG department had their own preferences and priorities that were fixed by their own department. A constant communication-to-inform process was necessary to make other departments open up to this project.

In 2005, six old test centres were closed and five new test centres were opened. The data for 2005 demonstrated the 11 hazard equipments were responsible for 83% of the whole production loss time. The preventive maintenance done on the equipment represented only 17% of the production loss. The opening of the new centers involved introduction of new technology that required new competency skills to make repair short in time. Pareto chart for operational maintenance done with preventive maintenance and number of work orders for 2005 is presented in appendix 3.10.

After analysis, 123 actions were identified and among which 109 actions were launched from 2005-2007. Reasons for not launching the rest of the actions include a lack of resources, less important or low priority for the PDL maintenance teams.

Twenty-nine actions were proposed for the development of departments that involved modification, evolution, improvement of a process, automation, installation of new solutions, safety, etc. Among others, I was involved in 11 actions that were mentioned below.

Installation of the supports for heating pipelines of emission equipments:

Deviation in measurements of the emission equipment was observed when it was moved from one place to another. At that time, there pipes were kept on the floor without any support and each time when they were displaced (either during cleaning of the center, or any other reasons), the test reading was not found stable. The development department was engaged to provide supports for all these pipes

and to fix them. This was helpful in avoiding that the pipes be in contact with the floor directly and in addition it reduced the variation in tests caused by these pipes.

Redefine operator's access to log in monitoring system of a test centre:

The maintenance computer specialist observed that operators modified the security parameters of some equipment during the tests to make their test run without any stoppage if the value exceeded the safety range values. After completion of tests, previous parameters were stored again. This was considered a safety risk for equipment. The development team was asked to modify the operator's system access parameters. In a new proposed login, no modifications were allowed in the parameters by any operator. A short training session was proposed by the LDG department for all operators to make them aware about this issue. The action helped to consider the PDL safety measures defined for equipment.

Improve the login interface for the operator: The initial interface to login the system for an operator was not very easy or user friendly. When the operator entered the system by the login, he was first required to find the path, then the folder and later on select the desired file. Afterwards, he was able to reach the login screen where he entered his login number and password. For new operators, it was less easy as compared to the experienced ones. The development team was contacted to improve the interface that allowed the user to enter the login and password from the first appearing screen. The rest of the actions were bypassed. The action helped operators to work with a simple interface.

Creation of reference tree for tests: The maintenance and development teams were engaged to create a reference tree for all specialized tests (a folder containing all reference files with respective folders and sub-folders). This was found helpful in organizing all test files and to search quickly in case of need. The action was to standardize the reference components of the files for each test centre and for the types of tests.

Space allocation to stock all source reference files and backup files: In case of work-orders, where the file used by operators to generate his results was not workable or corrupted, the maintenance team was required to replace the source file used to run the test by the original source file. For this purpose, the

maintenance team used the test source files that they had in the several forms (*i.e.* forms of CDs, or file on the server, etc). The development team was suggested to allocate some space for the maintenance team to store all these source reference files and the backup files on the server. The action was found to be helpful for providing solution in less time when all source files were available on the server. No other material like source CD or a copy was required to be found and used.

Bug in increment value of the Test Manager Program: Test results were managed by the *Test Manager Program*. These tests were automatically assigned to an incremental number by the *Test Manager Program*. A bug was found which disturbed twice the tests and no incremental number was assigned to the new tests. As a result, both results were replaced with old tests files because of the same number assigned. The development team was asked to consider the necessary steps in order to avoid such bugs. A meeting was arranged with the development team and the developer of the program to find the bug. All files with the bug were reported in a file to keep record and to identify possible reason for the problem. The file was sent to the developer of the program and a new patch was installed to avoid a future bug.

Automatic restart of Poolman: A software name *Poolman* was used to verify all the tests results. This software was then sent from all the resulting files to another software application for further manipulation and data treatment. Due to a large number of tests conducted in a relative short time, the *Poolman* was blocked twice a week on average. The development team was asked to change the program parameter to allow an automatic restart of this application in the case of a large number of tests on the waiting list. The action was helpful to the test how to avoid unnecessary halt/blockage of the system. Before, the maintenance team was required to restart this program each time when it was not functioning. The action helped PDL teams to avoid unnecessary stoppage of the test. In addition, the LDG team was asked to propose a new solution to avoid this reboot problem.

Modification of water presence sensor for safety in the heat exchanger: The existing water sensor allowed the operators to know the presence of any water particles in the heat exchanger. However, if the sensor was not connected, defected or not-activated, no safety check existed, thus, it was not possible to alert the

operator about the sensor's problem. The LDG team was suggested to modify the safety system. They were asked to add some kind of alert for operators if the sensor was not working, defective or not activated. The proposed alert was in the form of a light or vibration signal. The action was linked to safety parameters, thus, increasing the safety of the test equipment and proper working of the equipment.

Stock all software files and the drivers on the TeamPlace: *TeamPlace* was a solution provided by *Volvo IT* to facilitate information sharing, document management and collaboration. *TeamPlace* was a team website with no special software requirements. The maintenance team was proposed to stock online the software and drivers which they used for maintaining the equipments using software and drivers. The action was found helpful for using the online resources library quickly and to install or re-install certain drivers in case of need to repair quickly. Before, a maintenance team member had to look the desired software file at his desk, or other team's desk to identify the desired file for repair in the form of CD, etc.

Shared dictionary on the server: The dictionary contained the formulation to convert certain parameters and variables into readable data form. In the beginning, this formulation dictionary was not accessible to the ETO department and their data conversion resulted in errors if they did not use the exact conversion formulation in their resulting files. The development team was asked to share the dictionary on the server. The purpose was to provide an on-line support for the operators to convert their results into the desired formulation and to avoid errors in results.

Redefine and improve the import tool: An Import tool was used to download the unprocessed resulting data from all test centres. This tool did not work in the desired way and as a result, every week the ETO department asked the maintenance department to recover results that were not completely downloaded. Missing results were searched again from the test centre PC and each time, the maintenance team had to copy all missing files and then results were downloaded by the Import tool. There was trouble with some for maintenance in searching for all missing files each time. This often required more than two hours for this

operation. In addition, all files sent to servers were not able to be processed if the number of test results exceeded 15 at a time and then a reboot was required. The development team was asked to redefine the parameters and improve the functioning of the Import tool. The supplier of this tool was contacted and he proposed a new improved version of the tool. This helped the PDL to reduce 50 % of the problems concerning the tool.

8.9.2 Training

Various forms of training were identified and provided: work instruction sheet, standardized procedure development and explanations to appropriate personnel, maintenance guide, autonomous maintenance procedure and awareness messages. It also included update of a document, or a completion of the document. Reasons for various training include temporary, unskilled and less skilled ETO operators, ignorance of certain instructions, etc. 17 training actions were identified, among which nine were related to the autonomous maintenance for ETO operators.

8.9.2.1 Autonomous Maintenance training for ETO

Maintenance performed by equipment operators is called autonomous maintenance (AM). AM is defined by Nakajima (1989) as deterioration prevention [261]. McKone et al. (1999) defined autonomous maintenance by considering various quality goals [236]. In order to improve the collaboration between maintenance and the ETO department, autonomous maintenance was established. It included mutual efforts from the ETO and maintenance department, guidance and support from the maintenance team for ETO on common problems of equipment and involvement of operators who used the equipment. It was observed that 5% of work orders asked by ETO department were relatively easy to avoid if small verification by the operator was done on a regular basis. In some cases where the maintenance team was busy in other tasks or activities, these work orders caused an unnecessary burden on maintenance activities and generated production loss that could easily be avoided *i.e.* breakdown due to disconnected cable, equipment cable off, wrong parameters, reboot of equipment or computer,

etc). Various autonomous maintenance training actions were proposed to the ETO department that were the following.

Verification of proper functioning of Emission gas pumps: The pumps of emission gas were not checked on a regular basis, which could generate potential failure of equipment. A simple autonomous maintenance of verification of pump functioning was prepared by the maintenance department and was delivered to the ETO department to verify pumps on a regular basis. This training with simple procedures of verification was found important to ensure that proper functioning of the equipment and to alert the maintenance department if any deterioration was observed.

Changing the filter of emission gas equipment: The ETO team was asked to change the filter of emission gas equipment every week. The maintenance team conducted the training session for this process after creating the procedure. The training was to improve the functioning of the equipment.

Verification of all alarms before starting the tests: After five work orders in a week concerning the non-verification of alarms generated by the emission gas equipment, it was found necessary to clarify the problem. The development team was asked to conduct a training session for all the operation team members to verify all alarms and activate or deactivate accordingly before conducting the test. Various alarms were not verified by operation teams that stopped the test after a few minutes unless they are cleared or appropriate actions were taken. This training session gave a clear picture of all the alarms of the equipment, including why, how and when to use these alarms for the tests. Afterwards, work orders concerning alarm verification were minimized to 30%.

Changing the filter of particle sample trolley: The operation team provided the training for the autonomous maintenance to change the filter of the particle sample trolley that was due after each test. The maintenance team designed the training to change the filter and provided a training session to demonstrate and explain the procedure. The training resulted in improved filter functioning because of the changing of filters by ETO teams and reliable performance of the equipment.

Changing the filter of the fuel consumption meter: The operation team was given the training for the autonomous maintenance of changing the filter of the fuel consumption meter after regular intervals of operational hours. The maintenance team created the training session to change the filter and provided a training session to demonstrate and explain the procedure. The training resulted in no production loss for changing the filter as the maintenance was planned by the ETO team according to their test schedule.

Training of maintenance and operation departments on particle testing computer system: Both the maintenance and ETO departments were not familiar with the computer system of the particle testing machine. The training was provided by the development department about the utility and functioning of the system. The training was found useful in terms of knowing the equipment.

Calibration of the fuel consumption meter: Ten test centres used this equipment for fuel consumption measurements. Calibration of the fuel consumption meter *AVL 733S* was recommended on a daily basis by the manufacturer. An autonomous maintenance sheet was developed and provided to the ETO team for daily use. In three consecutive work orders, it was observed that no daily calibration was observed which was among the possible cause of deviation in the results. A recall was sent to all test centres to use the autonomous maintenance on regular intervals as described in the procedures. The message was delivered to the operational team in-charge to assure the proper calibration. As a result, regular calibration was done which was found helpful for smooth running of the tests.

Changing the filter of the fuel consumption meter: The operation team was given training for the autonomous maintenance to change the filter of the fuel consumption meter after regular intervals of operational hours. The maintenance team created training actions to change the filter and provided a training session to demonstrate and explain the procedure. The training resulted in no production loss for changing the filter as the maintenance was planned by the ETO team according to their test schedule.

8.9.2.2 Other training for ETO members

Fifteen instruction sheets for several equipment were prepared, explained and provided to the operation team that was found effective for quick diagnosis if problems existed.

Operator's training on their new login system for the test centre: All test centre operators were provided training on the new login access specifications. In their new login, they were not able to modify any security parameter defined for the equipment by the development departments. An awareness session was held to demonstrate its importance.

Operator's training on careful use of equipment in the test centre: All test centre operators were informed about careful use of the test centre equipments. Whenever they added or removed any instrument from the engine or any equipment, they were told to do the operation with great care without disturbing, displacing any other equipment which was not required to be. All these steps ensured the smooth running of the test and avoided any possible deviation.

Careful handling of temperature sensors installation on the engine: The instrumentation team was asked to help the ETO maintenance team when some sensors were found not working. During the investigation, it was observed that these sensors were not correctly mounted on the engine and were not carefully handled. Two of them were found defective because they were forcefully installed. The instrumentation team helped the ETO team to carefully and correctly install and use the sensors that were the cause of production loss. The training resulted in improved utilization of sensors.

Training on new tools for ETO team members: Whenever a test was completed, all test results were sent to another server that treated the test results with the help of any of the two tools. One was installed in 2004 whereas the other was in use for more than 20 years. Sixty percent of the operation team members were not familiar with the new tool. The LDG department was suggested to provide a training session for all the ETO department members. All other sites used the new tool. The training objective was to improve the knowledge of the tool

for the operation team and in case of any malfunctioning of the tool; they were able to explain well the problem and error to the maintenance team members.

8.9.2.3 Training for maintenance team members

Various types of training actions were identified and provided to the maintenance team members. Some of these were the following.

Awareness about heating pipes of emission gas equipment: Heating pipes are considered as the sensitive part of equipment that carries the gases for measurements. All the members of the maintenance department and ETO members (test centre operators) were made aware through the development team to handle these pipes with care. In addition, the development team provided support for these pipes to avoid unnecessary displacement.

Emission gas preventive maintenance: During corrective maintenance of an equipment (emission gas), it was observed that among others, a probable cause of deviation in the results of emission gas equipment was their filters which were found to be humid despite preventive maintenance done a week before. The maintenance store was contacted to establish the conditions of these filters. Some filters were found to be humid causing malfunctioning of the equipment. The preventive maintenance team was asked to verify the condition of the filter before replacement during maintenance. An email was also sent by the operational and backup office managers to all the members of preventive maintenance to remember this point. The message of awareness was found useful and no further humid filter was used in any preventive maintenance.

Display a calibration certificate on gas cylinder: Each gas cylinder was supplied with two copies of the calibration certificate issued by the supplier. The certificate was used to establish the calibration of gases in the cylinder. A copy of all these certificates was kept in a gas calibration file used by the maintenance department. The emission gas specialist who received these cylinders displayed a certificate on the cylinder that allowed him to identify the cylinder and calibration values of the gases. When another maintenance team member received the cylinder, he kept one certificate in the file and discarded the second copy of the certificate by considering it as unnecessary copy. During a repair activity by the

emission gas specialist, he observed that four cylinders were not carrying any calibration certificate. He was not able to enter the gas parameters in the test to immediately conduct a test. All these cylinders were identified from the file certificate enabling him to know the calibration value of the gases inside the cylinders. A message was sent to all team members to keep a certificate on the cylinder at the time of reception of any new cylinder. This operation was found important because the absence of any certification can harm the whole test in case if the values of gases were not known. The non-exact values could disturb the whole test results.

Display a procedure of purging the gas cylinder: In the gas cylinder stock room, three different procedures were displayed for purging the gas cylinders recommended by the supplier. The emission gas specialist was advised to keep a single procedure, which was the most recent one, and to discard the rest to avoid any confusion in the procedure. Only one standard procedure was allowed.

Training on gas emission equipment: Special gas emission equipment was installed to test US engines according to their standards were less frequently used in the past. Increase in demand of this test centre from 2005 to 2007 required appropriate training for the maintenance teams. The LDG department was contacted for a training session for all members in corrective maintenance. The training improved maintenance knowledge to the team members about that equipment.

Other training actions of maintenance team members: Various external training actions were arranged for the maintenance team members for different equipment and other subjects. It included training of software utilization, maintenance, English for technical purpose, maintenance approach, etc. Training in English was added for all employees and was beneficial at the time for communication with foreign teams in France. In 2006, four exchange visits were proposed between Swedish and French teams. These visits were to see the working methodology of both sites and to take advantage of best practices of both sites. As a result, the Swedish team provided training to the French corrective maintenance team about three equipment. Afterwards, a preventive maintenance team member visited the Swedish site to exchange preventive maintenance activities. Swedish

teams made two successive visits and discussed their maintenance department approach. The test centre in Sweden differs from France. In Sweden, all the test centres were constructed at the same time with huge investment. The construction of the test centres allowed the maintenance teams to select same equipment for their test centres. In France, the old test centres differ from the new ones in terms of equipments used to run the test.

8.9.2.4 Training for weekend maintenance team member

The weekend team was responsible for various activities concerning preventive maintenance for the weekend (Friday, Saturday, and Sunday). The team was used to gain time in the week to allow the test centre to remain operational. After observing the data for CMMS, it was noticed that 5 % of production loss was due to the unavailability of corrective maintenance team on the weekend. All breakdowns observed on Friday were not performed by the operational team in 2005 and the center was unable to run on the weekend in this case. The weekend team was established to carryout preventive activities only. No benefit could be extracted in the case of any breakdowns. It was planned to train the weekend team for breakdown activities.

Thus, the weekend team was provided with basic training on repair activities to handle repair on the weekend. As a result, repair activities were also started by a weekend team specialist. The reason to train a specialist was to continue maximum PM activities on the weekend. This was the primary purpose of the weekend team. By the end of 2007, 70 % of the repair activities were handled on the weekend with success.

8.9.3 Preventive Maintenance (PM)

PM was aimed at reducing the amount of corrective maintenance to a level that allowed other practices in the maintenance process to be cost effective in terms of production loss. At the time of verification of certain repair activities, it was observed that there was a need for more preventive maintenance than the actual one. Especially on a computer system, almost no preventive maintenance was found. Twenty-two actions for PM were added (calibration, checking and

verification of several tools, etc) for several equipment, out of which I launched nine that were the following.

Software files of the Emission Gas equipment: There were 10 test centres using this equipment. No PM of software files of emission gas equipment was done. As a result, a lot of temporary software files were stocked in various folders which slowed down the speed of results and the operation processing time was increased. After the specialist's advice, it was decided to conduct PM of identified files on an annual basis. PM included removal of unnecessary files and data backup of test equipment folder files. This PM helped to clean the unnecessary load on the system and a regular back up of system files.

Entry grids of "Horiba machine" analyzers of Emission gas: This equipment was served in four test centres. The air intake part of the analyzers was cleaned every six months. The heavy quantity of dust found was an alert to increase the cleaning frequency. PM was recommended every three months to clean the air intake part of the analyzers. The PM was added in the regular planning. This PM was found to be important to avoid dust on the analyzers and to improve the working of the equipment.

Data backup of important files of the central monitoring system (Morphée): There were 15 test centres using this monitoring system. The malfunctioning of several components of Morphée was observed after modification of several parameters during repair activities by the maintenance team. Data backup of important files of Morphée was considered important and to stock on the server like other important source files. PM of every six month was added for the backup of all necessary files of Morphée. A plan of PM was established by a computer specialist of the maintenance department. In addition, the procedure for the whole process was written and explained to the preventive maintenance team members.

Computer files of particle sampling equipment (PSS-220): This equipment was used in 11 test centres. No preventive maintenance of computer files was done for this equipment since its installation. Discussion with the LDG and maintenance teams resulted in adding PM to its computer files. Some important files were

proposed for data backup quarterly. The scan disk was recommended annually. The LDG team established the procedure and frequency for PM maintenance.

Calibration of urea flow meter: All the test centres, except specific test centres, used this equipment. The manufacturer of the urea flow meter recommended calibration every five years. However, the deviation of results of flow meter resulted in re-calibration before this recommended frequency. Afterwards, PM was added to calibrate the equipment on a yearly basis. The annual calibration helped the maintenance department to observe the yearly performance of the flow meter and correction done to find the deviation from the standard value.

Auxiliary system (air-conditioning): Eight test centres used this equipment. The auxiliary system acts as an air-condition system for the engine tests. No PM was done in the past for the auxiliary system. A PM plan was established and added on a yearly basis for compressors. Filter of hydraulic pump and gasket was also recommended to change every year. This annual PM helped the equipment to avoid early break down.

Generator (dynamometer) Siemens: The dynamometer was used to drive the engine and considered as the most critical equipment in the test centre. In 2005, wear and tear of its rollers was the cause of a major breakdown of a test centre and resulted in several days of production loss. No PM was done in the past for these generators. A PM plan was established and added on a yearly basis for all 12 generators of this type. PM helped to reduce the breakdown due to the failure of rollers in the following years.

Ventilation system of water room: The water room supplies water to all test centres and is considered as the critical system for all test centres. No PM of the ventilation system of the water room was found. It was decided to conduct PM of filters of the ventilation system that contained several dust layers on inspection. An annual PM plan was established and added to the ventilation system.

Pumps and piping system of the water room: The water room was installed in early 1970's. Due to degrading conditions of the piping and four pumps in wing one, there was a need to replace these pumps and all the piping system that

required 70 000 euros. An investment file was proposed to the PDL management to get sufficient funds for this maintenance. The acceptance of this plan helped the water rooms to undergo this maintenance. It was done in the summer holidays to avoid any production loss for all test centres during the annual closure of the engine test centres.

8.9.4 Standardized equipments

As explained in the section of the PDL test centres, there were three major types of test centres. Various types of equipments were installed in different test centres. The major reason for the different equipment was the difference in installation time. The old centers were built 30 years before. With the passage of time, new material and equipment was purchased for the new test centres. A variety of equipments made it difficult for the maintenance team to do their job. It required an increased expertise on a wide range of equipments. Moreover, spare parts of old equipments were found difficult to obtain and in some cases, the supplier said that the manufacturing of some old series of spare parts had been stopped. In such cases, the maintenance and the LDG departments were bound to look for an equivalent spare part or other solution to replace the existing one in case of breakdown.

The architecture of the test centres was managed by a team of the LDG department. The aim of the team was to standardize the test centres and equipments used for regulatory requirements of engine testing and to share these test results (standardized result formats) in various sites. A project was launched in 2001 to standardize various equipments was supported by the maintenance department to focus on maintenance problems associated with different equipments. Up to 2005, various decisions took place in the Swedish and French sites to harmonize the same type of equipment whenever possible. The purpose of the project was also to meet the latest standards defined by automobile industry for engine testing.

8.9.5 Collaboration with other departments

Collaboration among other departments was launched with open and thorough communication to develop a common understanding of the PDL organization's goal and departmental goals. In all meetings, we constantly communicated the reasons for collaboration, why it was started, how the PDL organization is affected by collaboration and what targets can be achieved through this collaboration. It was further stated, without that communication the real power of setting goals, envisioning, and planning was not unleashed.

8.9.5.1 Volvo IT

The Volvo IT was responsible to support all computer system and related solutions to the *Volvo Group*. The *Volvo IT* proposed several updates or replacements of certain solutions to increase the efficiency of the computer system or other reasons (security patch, etc). In exploring some work orders it was found that 3% production loss was due to the lack of collaboration with *the Volvo IT*. *The Volvo IT* decided to update all PC using Windows NT or older version of Window 2003. In one test centre, some special software programs were able to run only with Windows NT. A special software program was not compatible with the Windows 2003 version. The ETO department asked maintenance team to resolve the problem. When the maintenance specialist arrived, he observed that the software was unable to return in its original working mode and some measurements could not be retrieved. Production loss was involved and the maintenance department was unable to change the version as it was under the control of *the Volvo IT*.

Another example was the loss of connection from the main server. The *Volvo IT* on regular basis created backup files and installed security patches on various computer systems. In some cases, the connection between the server and rest of the computer system was lost or remained unavailable for a certain time. In this case, if a test was conducted by the ETO department it was not completed and some information was required from the server, then these resulting information were not able to be shifted from the main server to the working post of the test

centre and as a result, the operator was not able to collect all the information for the test on time.

The *Volvo IT* was contacted and a contact person was identified to communicate with the maintenance department in all cases before any modification and upgrading in the computer system of the test centre was done. The problems concerning network connection were discussed with the *Volvo IT* representative. The *Volvo IT* was told to inform the maintenance department in advance about the network problems in order to prepare for those problems in the PDL context. The *Volvo IT* assured to alert the maintenance department as soon as possible before updates or network problems. The *Volvo IT* work order problems were reduced to 25% in 2006 and 50% in 2007 after these efforts of cooperation.

8.9.5.2LDG department

From the problems observed by the maintenance members, it was identified that an increased cooperation with the LDG was required to avoid work orders concerning development problems. For 4 % of work orders in 2005, it was observed that the basic reason was a lack of cooperation between the LDG and the maintenance teams. Whenever, the LDG team developed any new test solution or function. It was first tested in one test centre to observe its impact and functioning. In that case if it was found effective, it was deployed to all concerned centers. In some cases, the maintenance team was called by the ETO department to repair or remove the abnormal behavior of the equipment. After detailed inspection, it was noticed that the parameters of equipment in that test centre was different from the other ones. Even the operator was not aware in 50 % of the cases about the development test. In that case, when an operator was aware of the test, he was unable to explain details about the solution applied. That increased the time of repair sometimes led towards a complex situation (maintenance team reused the old parameters and sometimes computer specialists got confused about the parameters of the other test centres, etc). A constant dialogue was established with the LDG group to provide a solution for these types of problems.

Increase in collaboration with the LDG department resulted in several benefits for maintenance management. The LDG department proposed a solution to increase cooperation with the maintenance department for deployed test

solutions in the test centres. The solution was the development of online software with a special login for the maintenance team to verify if any test solution was deployed in any of the test centres including all changes within the different equipment's parameters. In addition, in certain cases, the software allowed maintenance teams to download the test solutions for other test centres if required.

In all new and upgrading projects, a maintenance team member was assigned as a representative of his department. He was provided with the necessary details to inform with all members about the projects and he proposed the specifications of the maintenance department in all these projects to assure an effective maintenance of the new equipment. All new purchase required advice from the maintenance department.

8.9.5.3 ETO department

Sometimes, the ETO department did not send their feedback on acceptance or rejection for the proposed repair by the maintenance team. In 15% of these cases, it was observed that the ETO department refused the repair activity done and asked for repair to be done again on the same problem after a week or more. The maintenance teams did not appreciate this refusal of re-repair after a period of one week and refused to carry out work unless a new work order was issued. To solve the issue, the ETO department was contacted to finalize the rules for work orders. Before the migration towards the new *Coswin* software, the procedure of work order acceptance and rejection was clarified and finalized. The new procedure was written and sent to the ETO department for deployment. Training sessions were held for ETO operators. In this way, the ETO department was engaged in *Coswin 7i* to register their comments and to inform the quality of repair done by the maintenance team. It was helpful to know the status of the repair and feedback from operators. Details of working on *Coswin 7i* were presented in the section presented above namely CMMS. All repair activities required a validation from the ETO and maintenance teams before closing.

Cooperation with the ETO department resulted in deployment of 10 training actions for autonomous maintenance and other training to improve the maintenance of the test equipment. The maintenance team provided assistance at various occasions when asked during the breakdown of several equipment. It was

observed that the breakdown of a test centre was not due to any equipment. The reason was the bad manipulation of the test, negligence, or unable to perform the right task despite of the availability of all the testing means. It was termed as assistance (AS) by the maintenance department and the time for this maintenance activity was not included in the maintenance production loss time. Testing operation teams were provided the list of work orders which fell in the AS range and ETO managers were asked to prepare ETO team members for this type of work orders and production loss. In addition, another category was defined as “VERIF” which was different from “AS”. It was allotted when the ETO department was asked to verify the working state of equipment. If no problem or error was found during the verification time, the time was excluded from the maintenance production loss. MTBF, MTTR and ASS for 2006 is presented in appendix 3.9. Regular weekly meetings between operation and maintenance teams to exchange information, problems faced and repair in progress were planned and organized.

8.9.5.4POD department

The POD department was responsible for planning all the test centres with various types of tests and equipments required. PM was delayed due to change several times in planning by the POD department. This was due to the importance of the client’s requirements to conduct the test urgently. It was observed that an increased cooperation with the POD department was required to handle such issues.

The POD and maintenance department were brought in constant contact in terms of providing information about the test schedule of the test centres. The list of all these test centres with no test was provided to the maintenance department. Twenty percent of the preventive maintenance activities were done in the test centre when the test centre was not conducting any test in 2006. This means that the test centre was not asked to stop the test or advised to conduct the next test after the required PM. The objective was achieved with the help of the POD department after reviewing the planned schedule established for the test centres. In the year 2007, 22 % of the PM was done when the test centre was not conducting any test.

8.9.6 Spare Parts

During corrective maintenance activities, breakdowns continued for several days because of the unavailability of spare parts in some cases. On average 10 work orders required new spare parts per month that were not available in the maintenance store. Spare parts were purchased on an urgent basis. During this period, several temporary solutions were implemented either replacement by another spare part in some other test centre or by bypassing the functioning of that part of the equipment. However, the maintenance store in-charge commented once that there were spare parts which have not been used for some time and the guarantee of those spare parts was not valid anymore.

Thus, during the FMECA analysis, various spare parts list for equipment were identified which is further explained in this section.

8.9.6.1 Investment of spare parts of five pieces of equipment

A new project was launched to identify the list of critical spare parts for a large range of equipment and to know the minimum quantity required in the maintenance store. An investment of 130,000 euros was asked from top management to fund the project. At first, five equipment were identified for the purchase of various spare parts with higher production loss (cost of production loss was higher in the case of these equipment failures and production was halted because the equipment repair was long due to the unavailability of the spare parts in the maintenance store) and the number of work order demands. The goal was to make a quick standard exchange of spare parts (in order to repair the defective part of equipment in the minimum possible time) on a parallel basis. The average life time of these pieces of equipment was 10 years except for the industrial PC, which was estimated as three years. The spare parts were asked for the following equipment:

Siemens dynamometer was used in 12 test centres and is a major piece of equipment. Thirty-nine thousands euros were spent for the spare-parts. A 12-day saving of production loss was estimated through this purchase for the test centres.

Smoke meter AVL 415S was used in eight performance test centres. Seventeen thousands and five hundred euros were spent for the purchase of a new smoke meter. A 16-day saving of production loss was estimated through this purchase for the test centres.

Auxiliary loading system was used in eight durability test centres. Five thousands euros were spent for the spare-parts. An eight day saving of production loss was estimated through the purchase for the test centres.

NH3 measurement equipment was used in 10 performance test cells. Fifty six thousands euros were spent for the purchase of new NH3 measurement equipment. An 80-day saving of production loss was estimated through this purchase for the test centres.

Industrial rack PC used in 17 test centres. Twelve thousands euros were spent for the purchase of an industrial PC. A five day saving of production loss was estimated through the purchase for the test centres.

8.9.6.2 List of spare-parts of 20 equipment

A list was prepared for 20 key pieces of equipment according to their importance for the maintenance department (in terms of production loss, number of defects and nature of spare part). Then all the maintenance specialists of the equipment were consulted to identify the necessary spare parts in the maintenance store for corrective maintenance. After identification of the necessary spare parts, the minimum stock of these spare parts required was estimated from the yearly consumption and the critical importance of the spare parts. Afterwards, a stock level for purchase was identified. Various steps were studied because spare parts stock was a costly process that required a lot of resources including finance and material stock place. Spare parts had a guarantee period that was high because after that period, the supplier was not bound to replace the defective spare parts purchased.

Spare parts provision time was not the same for different equipment and suppliers. It might vary from a day to several weeks depending upon the stock availability, type of purchase (urgent, normal), supplier and time frame for the

purchase department and supplier location. Some equipment was supplied with a lengthy delay by the suppliers.

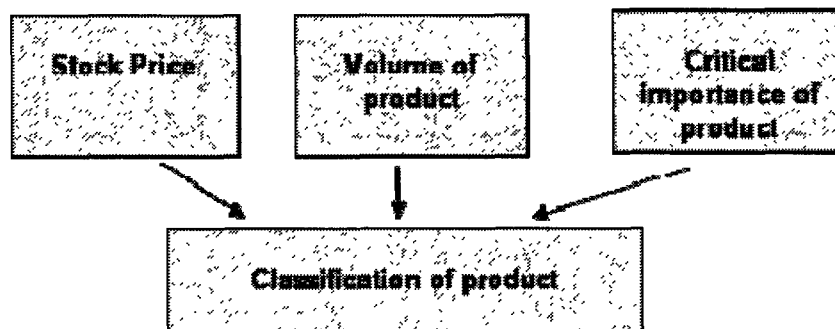


Figure 8-10: The classification of equipment was done according to the quantity of stock available, price of stock available and importance of the spare parts (critical or not)

Without knowing the inventory stock, a casual inspection at irregular intervals was among the possible cause in ordering more parts than needed. So an inventory control was done to establish the present stock twice a year. Two thousand and five hundred articles were shifted in CMMS to generate a database during the year for a one year period to December 2007. This was to easily trace the stock in the store.

The stock shifted in the database included information that included:

Article number: The automatic number generated by the system consisting of five digits. *i.e.* 60446;

Equipment: The equipment of the article if any. *i.e.* Smoke meter 415 S;

Description of article: The name of the article *i.e.* Smoke filter;

Manufacturer: Name of the manufacturer. *i.e.* AVL;

Supplier: Name of the supplier. *i.e.* AVL;

Supplier reference: Reference of the article given by supplier *i.e.* MF0478;

Location in the store: Location in the store of the article *i.e.* AVL 2.5

Quantity available: Quantity available in the store *i.e.* 19

Price of the article: Price of an article *i.e.* 3.40 euros

Minimum stock required: The minimum quantity required in the stock *i.e.* 3.

Remarks: Any other information about the article. *i.e.* A filter packet contained five filters.

The maintenance store was proposed as a way to manage the preventive maintenance stock. Once the quantity consumed, delivery time, demand per unit of a spare part was known over a fix period, it was possible to define, the security stock level and refill the level of that spare part. The stock target was the maximum quantity required in the maintenance store. The refill level was to ask for purchase of the spare part in order to attain the stock target. The value was based on the delivery time of the product supplied. However, in all cases, security stock level was required to be maintained. A 30-equipment spare parts list, which cost about 500,000 euros with details, was delivered to mechanical store in 2007 with the minimum stock of spare-parts, supplier reference, supplier deadline, etc to update the data base.

8.9.6.3 Audit 5S

5S audits were conducted in the maintenance store to improve cleaning, sorting and arranging of the working environment. The 5S is a five-step process with an aim to improve safety, cleanliness, organization, morale, and efficiency. It aims to facilitate ergonomic opportunities within the workplace. It involves employees of maintenance store to directly work in the area by giving them an opportunity to actively participate in shaping up their workplace. (Refer to section 6.3.3.3 for explanation of the words of 5S).

8.9.7 Documentation

While carrying out maintenance activities, the maintenance teams found that documentation concerning the material was not always available. It lacked

sometimes, technical documents about the equipment characteristics, diagrams to understand the electrical circuit, absence of documents that was available a few days back, missing maintenance guide documents, etc. Documents were not managed in one place and sometimes documents asked by other department for consultation were not placed in their proper place thus made it difficult to find documents quickly. After discussion with the maintenance management, a proper place was assigned for all the maintenance documents.

All new projects were not accepted for maintenance if documentation was found missing or incomplete (maintenance guide, maintenance training material, equipment design maps, etc). For other missing documents, the LDG teams were contacted to take a copy and all available copies for equipment were kept for the maintenance record.

8.9.8 CMMS

8.9.8.1 Upgrading from Coswin 5i to Coswin 7i

Upgrading of CMMS was done from *Coswin 5i* to *Coswin 7i* version in 2006. The new structure of equipment was defined in a new version with the help of maintenance specialists. All team members were constantly asked to correctly use the *Coswin 7i* software to fully explain the repair activity done to resolve the breakdown. While studying the data for the year 2005, it was observed that repair activities could be better explained. This was helpful for other people consulting the work order to know what was done during the repair activity. In addition, the information was useful to recover the necessary information when experiencing the same kind of problem somewhere else or with the same equipment in the future.

The new version was useful in terms of exploring more features and more elaborated structures for the maintenance department than the old version which was used at the time of creation of maintenance department. Some data were not transferred in the new version (for test centres that were closed in 2006) which created a difficulty at the end of year at the time of data comparison for the year 2005 and 2006 from the *Coswin 7i* tool. Both years' data were not comparable in

the new tool due to the absence of some data. The operational manager extracted the data from the old tool and finalized the yearly report. However, from August 2006, when the new tool was used, the operational maintenance job and repair activities were clearly identified in terms of data verification and repair time mentioned in the tool.

8.9.8.2 Training of PDL teams for Coswin 7i

Orientation of the maintenance team members concerned with the *Coswin 7i* was considered a necessary step once the PDL management decided to migrate the version from *Coswin 5i* to *Coswin 7i*. Orientation differs from training as it was considered as informing people what was going to be done or what was being done, while training was instructing people in how to do something.

Training of people was considered a critical aspect for the implementation of the new CMMS version. Training was asked for all PDL departments from the CMMS project in-charge that included:

- How to write a work order?
- How to define the priority order?
- How to assign different phases of work order?
- How to enter time for production loss?
- How to access and select the equipment and test centre in the work order?
- How to use the cockpit or dash board for all the departments according to their requirements?

8.9.8.3 Reports development from Coswin 7i

I was involved in conducting various studies concerning production loss and number of repair activities done by the maintenance department with the help of the *Coswin 7i* database. A new software *Crystal Report* was installed for the maintenance department PCs to exploit the data of *Coswin 7i*. I gained a fair knowledge of the software and participated with in project by being in-charge of

“CMMS upgrading project” to understand the utilization of the software. Afterwards, I was able to extract different reports for the maintenance departments. These included reports of:

- Top five/ten equipment in terms of production loss weekly, monthly, yearly and over a selected period;
- Top five/ten equipment in terms of number of work orders weekly, monthly, yearly and over a selected period;
- Details of a work order by its number;
- Details of work orders in progress for the ETO department;
- Details of work orders in progress for the LDG department;
- Top ten equipment in terms of production loss and number of work orders over a selected period for any test centre;
- Number of spare parts asked by the operational maintenance team;
- Number of spare parts asked by the back up office maintenance team;

These reports were used by the management to analyze the production loss, work orders according to the critical equipment and test centres. These reports provided information on a regular basis in the form of periodic reports and were also linked with the *Coswin 7i* screen.

8.9.8.4 Warranty and serial number for equipment

In the *Coswin 7i*, various pieces of equipment’s warranty dates were added after consultation with the maintenance store. It was a sort of information for the maintenance team if the equipment or spare parts was still under warranty. In case of a valid warranty, the contact with the supplier was quickly made to investigate the problem.

All pieces of equipment were identified by a serial number in the *Coswin 7i* structure. This was useful when equipment was shifted from one test centre to another during corrective maintenance. With the help of the serial number, the

movement of equipment was monitored. For any due PM in any test centre, this facilitated the place of that equipment thus avoid any redundancy in PM for the shifted equipment.

In addition, all PM actions were entered in the *Coswin 7i* which made it easy to assign and verify the equipment and functions for the due PM and already done work including saved detailed actions. The combination of these benefits led to increased control over maintenance operations. In the past, accessing this information for PM was not done quickly and confirmation of actions done was updated in the Excel sheet only. It was not found updated regularly. Thus, this use of the CMMS results improved management control of day-to-day functions. With these resources, the maintenance managers were better informed and able to take action before problems arose, rather than waiting passively for the next crisis.

From October 2006, a daily meeting was conducted by operational the maintenance manager to discuss issues related to the maintenance problems. It was found very helpful to know the breakdown, their reasons, solution proposed, difficulties faced, and an exchange of data from the *Coswin 7i* and *Crystal Report*. The daily meeting was focused on major breakdowns and a weekly meeting was proposed to discuss the performance of the week. The benefits of these reports were to improve communication-to-inform process and access the daily activities.

8.9.9 Suggestion system

Another important form of individual involvement was manifested in the form of a suggestion system. Suggestion system is used to collect suggestions from employees to make improvements in work. Japanese style suggestion systems emphasize positive employee participation [166] to improve work place. I proposed a format for the maintenance team members to present their ideas for improvements. This was to carry out the basic improvement activities inside the maintenance department. I discussed the idea with maintenance managers and then presented it to the maintenance director who agreed to the suggestion system plan. The format was finalized. It included the nature of the proposition, teams or departments required to participate, associated equipments or the test centres if

any, description of the proposition, the way in which that proposition could help the department, explanation with the diagram if any, advantages and limitations of suggestion, time required to implement the proposition, the teams or departments who will be benefited from the proposition, and reason for suggestion. The idea was proposed in 2007. It was discussed with all team members separately and collectively to consider their remarks. Then the template file was proposed to the maintenance department in a meeting with all team members.

Ten suggestions were proposed including safety, equipment, process. Some suggestions are presented below.

Suggestion 1: The vibration module was installed inside the test centre. During the test, nobody was authorized to go inside the test centre. In the case of adjustment of the parameters of the vibration module, the maintenance team had to enter the test centre to make the necessary adjustments. However, it was not possible when the test centre was running the test. During the test in operation, nobody was allowed to enter because of safety reasons. The LDG team was asked to take the necessary measures to install the vibration module outside the test centre. The proposition helped the maintenance department to verify and adjust the vibration module without stopping the test centre thus gaining the time.

Suggestion 2: Another suggestion was to increase preventive maintenance of pressure gauges in the test centres. Pressure gauges were calibrated every six months. During PM in a test centre, resulting values of some pressure gauges were found to be deviating to the tolerance range. It was proposed to increase the PM every three months. However, it was advised to do PM for one test centre and observe the results. In the case of major deviation, the PM would be increased and deployed for other equipment.

Suggestion 3: The smoke meter installed in the test centre used pressure sensors that were welded on the master control card. In the case of repair of the sensor, the maintenance team had to remove all the welded points and then the new sensor was welded on again. This causes the wear and tear of the master control card. A simple solution was proposed to connect the sensor with the help of support outside the control card rather than welding again and all connections were

made with a small wire bus. After this modification, no welding was required at all. In addition, the repair time was reduced.

Suggestion 4: All particle sampling machines were calibrated for air and gas dilution values at two different scales. The display screen mentioned only their last value of calibration. ETO teams were not aware of the first values of calibration unless they contacted the maintenance team member who had done the calibration. A display card was pasted on the machine mentioning both scale calibration values. This simple suggestion was useful for operators to know the calibration values to use in the test.

8.9.10 Other action plans

Skill Matrix chart: A skill matrix chart for the maintenance teams was defined for all the test centre equipment and was sent to all the PDL departments. The objective was to demonstrate to the PDL team the versatility of the maintenance team in maintaining different sorts of repair. In addition, it was helpful in assigning tasks for the maintenance teams according to the specialized areas.

Specification definition for the maintenance department: A clear list of activities was defined by the maintenance department in the form of a file including the maintenance department's requirements for all new projects to be maintained. The specific definition was found useful for other teams to understand maintenance requirements (equipment dismantling diagram, identification of critical spare parts, working conditions - safety, difficulty; description of tests to be performed after repair activities, plan of optimized and adapted preventive maintenance with procedures, autonomous maintenance operations, trainings, guarantee, etc).

Single contact number: A single contact number of corrective maintenance team was provided to all departments. The advantage of a single contact was to manage available resources and to prepare actions for repair activities in the least possible time.

Other possible types of maintenance: Maintenance is currently done on test bench availability. It often required changing the schedule if a test was in progress. A study was done to know if the maintenance could be done equipment wise instead of test bench wise. However, the idea was dropped as it involved more resources to conduct this type of maintenance.

Supplier maintenance on the weekend: The supplier responsible for maintenance of certain equipment worked during the week days (Monday to Friday). A study was conducted to observe if the supplier was asked to perform some preventive maintenance on weekends. The study demonstrated the usefulness of the PM on weekend is possible if the PM done by maintenance department itself was continued on the same days along with the supplier on the same equipment. However, due to the lack of resources, the idea was dropped.

Test centre capacity was defined as the opening of test centre in the year to conduct tests. Production loss in 2005 was 231096 hours for all test centres that represented 10.5% of test capacity. In 2006, production loss was 21833 hours that was 11% of the test capacity. It should be noted that from 2005 to 2007, four team members left the maintenance department. 1958 work orders were handled in 2006 by maintenance in test cells that was 1967 in 2005. Data for 2006 demonstrated that four out of ten equipment production loss was reduced from 2% to 10% as compared to 2005. However, the change in calculation method by the PDL maintenance made it difficult to compare these results. In 2005, production loss was calculated for the opening hours of test centres. From 2006, the calculation was changed and production loss was calculated for 24h a day and 365 days a year. Software test description loss was increased because of the lack of interface command communication between some newly installed equipments and the controlling computer system. It was reduced in 2007 after deployment of various computer solutions to 2%. The overall actions provided reduction in production loss except for five breakdowns for which spare parts provision time was about three months. These failures severely impacted on the whole production loss in 2006. Otherwise, the target to achieve lower production loss with respect to test centre capacity was possible. All the proposed actions were considered on a permanent basis. This demonstrated the importance in PDL strategy. This included autonomous maintenance, trainings, CMMS, maintenance store, etc. Production

loss in 2007 was reduced to 3% as compared to 2006. It was further stated that the improvement plans and actions played their role in reducing production loss. However, it was difficult to say which improvement played more of a role than others. It may possible that the reduction in production loss and improvement was the result of some other factors that were not considered or remained inaccessible from us in our proposed study.

8.10 Conclusion

This third case study aimed at understanding the QM implementation in our study of an organization for which *Volvo Powertrain* was selected.

It was concluded that focus on quality elements presented in the previous sections (people- top management, employees; process; strategy; customer focus and supplier) could be used to evaluate an organization's QM system (to identify weaknesses, and to assist the organization in formulating an improvement plan). However, these quality elements alone cannot overcome the problems that exist in the organization concerning the implementation of QM. A common roadblock that prevents an organization from successful implementation of QM is a weak culture of quality awareness in team members that acts as the real barrier to implement proposed or existing organization's QM in everyday activities. Without the integration phase, employees cannot use the quality tools in their daily routines. As a result all plans from top management remains short lived. The implementation of QM does not have to be accompanied only by pieces of paper that document all major processes. This is a requirement for all ISO standards to maintain a high level of documentation. However, the spirit of the whole documentation is not to satisfy auditors at the time of audit or to get certification only. The study demonstrated that the level of QM implementation depends on three steps: quality integration, everyday use of quality, and system evaluation for continuous improvement. More focus on these steps would represent a higher level of QM implementation in the organization. Low level of implementation was meant as less focus on these steps that in turn resulted in a high risk against QMS. Thus, the study of QM implementation developed in this study was at least applicable to this organization.

A quality approach in maintenance represents a major shift in the way an organization approaches the maintenance function; from being the sole responsibility of the maintenance department it becomes everyone's responsibility. For this purpose, various actions were proposed where the focus was on the different types of maintenance (autonomous maintenance, preventive and corrective), improved maintenance program followed by increased training to improve skills, improved usage of quality tools (FMECA, CMMS, etc), standardized equipment usage, increased cooperation among different teams to a communicate-to-inform process, integration of all actors of QM with communication, and increased communication to consider improvement actions for everyday use. During the whole process of QMI, employees need to know where they stand, what they do and what will happen next more than ever. If communicate-not-to-inform process is used, QM standards, procedures and even improvement actions may be ignored and resources may be allocated for accomplishing secondary actions. The communication-to-inform process is imperative for the QMI to communicate employees the kind of changes the QM will cause to their responsibilities and working environment. The quality awareness development is helpful to make top management and employees understand the shared vision of different parties involved in the QMI.

Maintenance was not merely preventive maintenance, corrective maintenance or autonomous maintenance, although these aspects were important ingredients. A quality approach for maintenance management was followed which required a careful fit to all concerned departments (*i.e.* in this case - the ETO, LDG and POD departments along with the maintenance department). The organization was approached to serve maintenance management with a quality approach because excluding or minimizing quality implementation phases not only reduced the benefits in improved performance but also increase the risks of a low implementation level of quality. It was essential to evaluate and analyze the maintenance management in the same manner as the other areas in the organization. This case study endeavored to highlight some aspects of QM implementation.

The organization embraced our quality approach as a key strategy for their activities for the PDL department. The case study concluded that less focus on QM

elements appeared in a weaker implementation of QMS that in turn makes it difficult to solve quality problems. Weaker implementation was visible in the form of improper usage of quality tools, lack of a communication-to-inform process and low employee involvement. Top management was the major player to unite together all elements. A QMS cannot be accomplished without quality implementation phases. Therefore, it can be stated that QM elements are supported by the QM implementation phases to solve quality problems. Moreover, a QMS is required to be reexamined over and over again as new information appears in the evaluation phase of the QMS. As more and more of the weaker areas are identified, new grounds for improvement will appear to increase the implementation of QM. With an employee's involvement in the process, QM implementation cannot be achieved without a culture of quality awareness. Awareness requires continuous focus on training, notably the importance of usage of QM in daily usage. Increased "quality awareness" is the result of a dynamic of functional certitude-incertitude to ensure constant and controlled change and clearance of tasks to be done and the strategy to be implemented. In effect, increased quality awareness also creates a certain form of functional incertitude that encourages employees to question their working habits that may not be efficient. In both cases, it leads towards improvement in the workplace. An organization's strategy is required to be widely set in a communicated-to-inform process to reduce dysfunctional incertitudes between employees and their management.

Top management sponsorship was required to realize the action plans with involvement of people through appropriate training to manage all processes and make a viable interface with QM implementation. Successful implementation of QM enables organizations to reduce quality problems while simultaneously identifying weaker areas for improvements. The realization of these benefits can provide a significant competitive advantage if a careful implementation of QMS is done. In order to gain this advantage, it is important to implement a comprehensive QMS initiative that includes all quality elements to strive for continuous improvement.

9 QM Implementation Modeling for industry

9.1 Introduction

The objective of the research was set in chapter one. The answer to the research objective is presented in the following sections. It seems to be possible to implement a QMS in industrial environment with the help of the model presented in this chapter. This chapter sheds further light on the development process and the evolving ideas about the QMI. The development process of the QMI is made explicit and it will be argued that the process itself followed a guideline. The iterative nature of the QMI development is also described in order to give a broader picture of the QMI process. The QMI phenomenon observed in an industrial environment through three case studies (refer to chapter six, seven and eight) and the literature survey (refer to chapter two, three, four and five) presented earlier, allow me to develop a model for implementation of QM. This chapter seeks to finalize the thesis objective. It identifies the QM practices, and presents a model for QMI. It presents the identification of QM practices, and the development of a model for QMI. Section 9.2 presents the identification of QM elements with the help of the specialized literature as well as the three case studies presented in the previous chapters. Section 9.3 provides the model of QM elements in the industry. Section 9.4 presents the phases of the QMI in the industry. Section 9.5 describes the model formulation for QMI phases. Section 9.6 explains the role of the QMI model in this study and provides research considerations. Section 9.7 describes the contribution and assessment of this study with its limitations. Section 9.8 summarizes this chapter.

The QMI is of great importance in terms of its dimensions and impact on business. It steers the organizations' focus on personnel involved in operations and allows a broader understanding of the competitive context [75] [87] [175]. QMI must provide priority to customers' satisfaction and, therefore, it is regarded as capable of sustaining the development of a QM strategy that aligns the organization with its various relevant publics [271] [271].

Successful implementation of QMS and resultant impacts on industry depends on a variety of factors. The ultimate shape and success of QMS implementation depends upon and emerges from a complex, multi-dimensional interaction between QMS and organizational users. In order to understand

profoundly the outcome of QM implementation efforts, one should consider the relationships among quality elements, communication and how they affect each other. In this thesis, we report results from our various case studies based on a study of industrial operations with organizational QMS through three case studies. We also provide some preliminary information on modeling quality, relationship between quality elements, communication and implementation phases and the impact of QM implementation. We coin three terms for QM modeling: quality elements, communication to inform process and quality awareness culture.

Our research objective is the understanding of QM implementation process in industry. For this purpose, we identified some QM elements with communication in organizations (presented in chapter two and three). Based on this identification, part of the research objective is to study how QM implementation phases can be achieved. This is not a simple issue as indicated in the literature review, which indicated that different researchers adopted different indicators for QM implementation.

9.2 Identification of QM elements

The identification of the quality elements for QM was done with the help of two different sources *i.e.* literature survey and industrial case studies. Chapter two and three summarized the role of communication and quality elements in organization from the literature review. Specific organization's QM standards were also studied that reflected the characteristics of constructive case study results (refer to chapter four and five). The research strategy summarizes all the phases for the study conducted (refer to chapter one) and introduces the suggested methods for fulfilling the criteria for an operational and viable model. Later, in Chapters six, seven and eight, QMI was studied with the help of three case studies to further verify and evaluate if the research and the construct were capable of fulfilling the construction of a model. After going through a literature review presented in chapter two, three, four and five, the QM elements that affect the implementation of QM were identified and listed below.

- 1- Top management
- 2- Employee's training

- 3- Strategic quality planning
- 4- Customer focus
- 5- Process management
- 6- Communication-to-inform process.

The detailed description of the quality elements is presented in chapter two and chapter three. Thus, in this study, QM is composed of six elements or quality dimensions that are required for a QMS. Implementing a QMS is possible by deploying these elements in the implementation phases. Our model is based on these six elements. These quality elements contribute to the implementation of QM and a research study has been conducted on these elements of QM. A QMI study was originally conducted to design the implementation phases in organizations. As stated in our case studies, the objective of the QMI was to understand the QM elements and QM implementation process to help organizations implement QM activities. For clarity, the quality elements summarized above are reviewed again below.

9.2.1 Top management

There is a shared agreement in quality literature about the decisive role played by top management in effective implementation of QM [87] [368], which significantly interacts with other QM practices [238]. We have demonstrated that no improvement action plan was possible to implement in the case study organizations without the commitment of top management of organizations (*i.e.* acceptance of action plans to be implemented by the top management was the first condition to work on QMI – in the case studies presented in this research, top management was found committed to work on the proposal for implementing the QM standards, refer to section 6.6, 7.8 and 8.9). In chapter six, it was observed that various quality activities (JES, SOPs, work post audit verification, skill matrix charts) were not systematically used by employees because employees were not aware of the importance of these QM activities. Top management was responsible for ensuring that all the necessary documented procedures addressing all critical

issues were planned, verified and applied. It is urged that top management is not meant to provide only quality tools but to strongly encourage people to actively use those quality tools for process management. The same case study was observed in chapter eight where we have seen that the lack of awareness of the importance of quality tools (CMMS and FMECA) resulted in their inappropriate usage (refer to section 8.9.1 and 8.9.8). We have seen in chapter seven that employees were not aware of the proper usage of tools for file management even when data were increasing at a rate of 50 % a year. Top management was responsible to provide appropriate training for utilization of these tools for QMS. From all these case studies presented in this thesis, it is concluded that top management carries the responsibility for commitment to QM and willingness to support employee's quality efforts necessary to achieve the goals. Thus, we identify top management as an element of QM. This leads us to declare that: **Less the QMS is accompanied by top management, less the problem of the QM implementation is solved.**

9.2.2 Employee's training

Many research results reveal that employee's training is one of the most important elements in a successful implementation of QM [225]. The major focus after the evaluation of the QMS of case study organizations was to provide the training to all employees (refer to section 6.6.6 for details) where training on SPC, ISO 9001, 5S, etc were proposed to employees of engine assembly shop in the first case study. In the second case study (refer to section 7.8.3), after evaluation of the QMS and practices observed, continuous training on file management was recommended for all employees to avoid any abrupt increase of data in the organization. In the third case study (refer to section 8.9.2), various types of training were identified and provided: work instruction sheet, standardized procedure development and explanations to appropriate personnel, maintenance guide, autonomous maintenance procedure and awareness messages. Seventeen training actions were deployed in three departments of the PDL that was helpful to reduce the production loss associated to those actions. Through participation, a shared understanding and commitment for QM is created, and for this purpose, continuous training facilitates employees learning to implement the QM system.

From all these case studies, it can be concluded that training should be viewed as an ongoing process to cultivate the learning behaviors in employees that is necessary to continually implement QM improvement as a continual process. Simply put, QMI is both a process and an outcome, with one acting on the other and vice versa. It is further urged that in organizations there is a need to acquire prevention training before the quality problems occurs rather than to control the problems later when the damage is done. Employees require training at the same time when quality tools are deployed in the organization. Thus, we identify employee's training as an element of QM. This leads us to declare that: **Less the QMS is accompanied by employee's training, less the problem of the QM implementation is solved.**

9.2.3 Strategic quality planning

The intent of a strategic quality planning is to communicate the organization's values, aims and ambitions, so that employees can make decisions that are consistent with and supportive of these objectives [241]. We have explained in chapter six how the quality policy was communicated to all employees of the engine assembly shop. All team members were given a briefing about the organization's policy that aimed at being helpful in the deployment of policies and achievement of objectives. In case study three, it was suggested to explain the necessity of strategic decisions to all concerned employees for the maintenance department to prioritize the maintenance tasks (refer to section 8.7.2) in the light of the PDL management's strategy. The findings of our second case study explained that strategic quality planning is required to be communicated in the organization to engage employees in achieving the quality objective. While working on file management, it was observed that employees were not aware of any policies or procedures about file management tools (eRoom, share folder, public folder – refer to section 7.8.1 for details). No precise rules and guidelines were provided to take full advantage of these tools. From our case studies presented here, it is urged that strategic quality planning is important for understanding QM. Organizations are required to promote successful communication and help employees to work for the necessary changes of QM

activities by focusing on the strategic quality planning. Thus, we identify strategic quality planning as an element of QM. This leads us to declare that: **Less the QMS is accompanied by strategic quality policy, less the problem of the QM implementation is solved.**

9.2.4 Process management

Many researchers stress the importance of identifying suitable process quality improvement opportunities because of their significant impact on cost reduction and quality improvement [331] [7]. It was deduced from the results of case study one that use of quality tools and techniques required continuous training to manage process. The quality tool utilization like SPC was meant to optimize process deviation and improve process results, however, internal audits revealed that team members were not well informed about these tools. Process management required continuous training and engagement of employees in performing the job to avoid any process variation. It has been seen from the case study one that communication is important to inform employees about the process attributes to understand and to follow the standardize procedures issued for this purpose. Training for all employees was provided twice to help employees manage the process. Similarly, in case study two, it was observed that the effectiveness of file management tool remained limited because the utility and sharing of information through these tools were not well explained to the employees. It resulted in the generation of huge data in a year due to the lack of understanding of the tool and its capability within the organization. Likewise, focus on the process management was done in case study three where 13 work instruction sheets on different equipment were provided to the ETO department (refer to section 8.9.2) to manage the process in optimal working conditions. In addition, we have seen in chapter eight that process management required sponsorship from all teams (*i.e.* cooperation among the LDG, the ETO, the POD and the maintenance department for case three) and a lack of collaboration resulted in a loose grip in the management process and higher production loss was observed in 2005 as compared to 2007 when cooperation among the PDL department was increased (refer to section 8.9.5 for details). From all these case studies presented in this

thesis, it is concluded that process management to produce the desired output is the combination of employee's effort and available tools and techniques for which training give the requires level of process control. Employee's continuous training in the use of techniques and tools highly determine if a process is 'in control' or not. We have explained in section 6.6.3 where the employees, after appropriate training, were able to better handle the process and improved the utilization of quality tools. Thus, we identify process management as an element of QM. This leads us to declare that: **Less the QMS is accompanied by process management, less the problem of the QM implementation is solved.**

9.2.5 Customer focus

Customer focus is the underpinning principle in the QM and has the strongest significant predictors of operational performance [313]. Companies such as *Chrysler*, *General Motors* and *Ford* established customer needs as a top priority and initiated QM programs [88]. It can be deduced from the case study three that monitoring the customer focus until satisfaction required the evaluation of information relating to customer feedback to know if the service provided has met the customer requirement. The ETO department was considered as the internal customer of the maintenance department was continuously contacted with the help of CMMS to monitor their requirements. All services provided to the ETO department by the maintenance department were regularly analyzed, and actions were proposed to improve the maintenance and operating services for the test centres. Customer focus asks for continuous communication to inform customer about the services provided and their feedback is used for improvements. In case study three, the ETO department was informed for all the work orders done and their feedback was stored in the CMMS to analyze the service provided. For case study one, where the test centre team was the internal client of engine assembly shop was contacted to receive the feedback on engine assembling. The feedback was then processed to know if any necessary corrective or preventive action could be taken. This concept was helpful for employees in better understanding customer requirements as inputs. It can be concluded after the case studies that monitoring of customer requirements until satisfaction requires the evaluation of information

whether the process has met those requirements and is helpful in implementing QM. Thus, we identify customer focus as an element of QM. This leads us to declare that: **Less the QMS is accompanied by customer focus, less the problem of the QM implementation is solved.**

9.2.6 Communication-to-inform process

The communication-to-inform process is the bond that holds all these quality elements (top management, employee's training, strategic quality planning, process management, customer focus) in an organization together. The communication-to-inform process helps the provision and the availability of quality information for all employees in the organization. The availability of quality information is vital for effective and efficient QM practices [300] that helps top management in making decisions [238]. We have mentioned in the case study two that continuous communication and interaction between *ISQV* quality department and *IS* teams was utmost to obtain the desired organizational quality goals. For this purpose, the intranet of *ISQV* was developed to enhance the quality efforts of the *IS* organization in order to promote its quality objectives. Various quality issues related to CSV, CM and regulatory audits were presented on the Intranet to provide a channel of communication inside the organization. Moreover, we have presented in chapter six that the major weaker point of the engine assembly shop was their communication-to-inform process that was required for a good cohesion between teams to carry out the required tasks according to the SOPs (refer to section 6.4). The quality department introduced SPC charts to monitor the process stability, however, these charts were explained only once to the employees who were using these charts. People were not aware of its utilization and were not able to take advantage of this tool. In our improvement action plan, we indicated the necessity of effective communication to demonstrate the importance of SPC charts and appropriate training to use the SPC charts. The gap between QM documentation and QM implementation practices was reduced with the help of communication-to-inform process. The SPC charts after two training sessions demonstrated that team members were using the SPC charts (refer to section 6.6.6) in a better way than before. All TM were invited to discuss and improve the SOPs

that paved the way to engage the employees in implementing the QM. Same results were attained in the case study three, where cooperation among all the PDL departments was increased due to communication-to-inform process. The case studies explore the issue that the communication is considered as the foundation for QMS on which the whole building of QM is constructed. Once the communication-to-inform process is integrated in the QM, then organizations can be transformed towards full implementation of QM. Otherwise, lack of communication in organizations blocks all routes to advance towards successful implementation of QMS. It is concluded that the communication-to-inform process is very important to make all elements of QM interact with each other. Thus, we identify communication to inform process as the glue for quality elements in a QM. This leads us to declare that: **Less the QMS is accompanied by communication-to-inform process, less the problem of the QM implementation is solved.**

9.3 Model for QM elements

Based on the above six hypotheses, a model of QM elements was developed and is presented in *Figure 9-1*. The links between top management, employee's training, customer focus, strategic quality planning, process management and communication to inform process are incorporated in the model presented below.

In these six hypotheses, different QM elements were taken for QM implementation. In the sixth hypothesis, communication to inform process, the relationship among the first five hypotheses with the sixth one is studied. In this model, communication-to-inform process unites all the other quality elements. To the best of the author's knowledge, no researcher has proposed such a model in studying the comprehension process of QM elements in the industry with QMI.

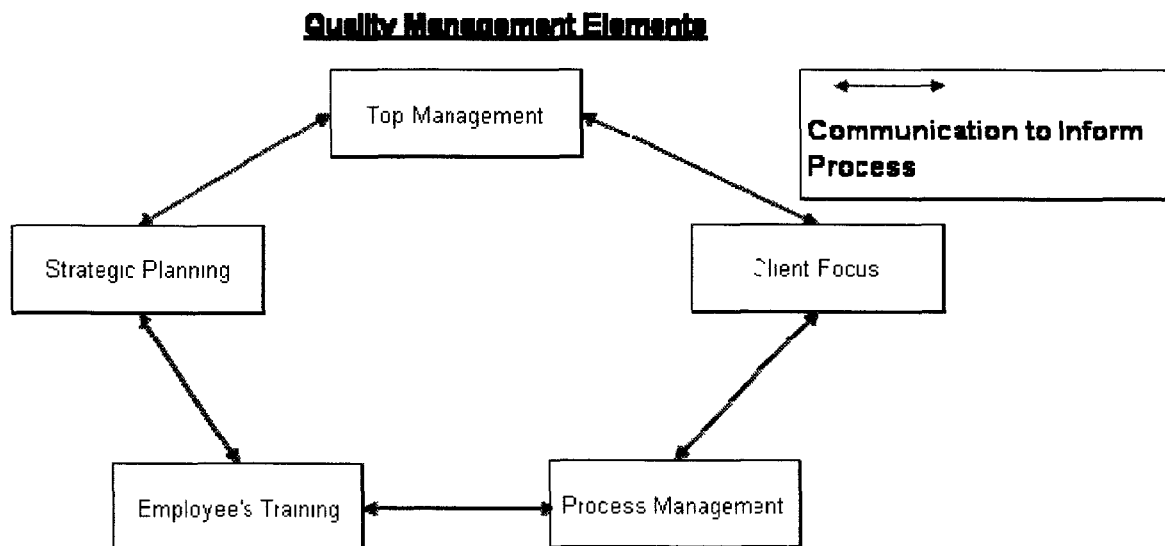


Figure 9-1: Quality Management elements in organizations

The top management in this model provides employees the strategic quality planning to manage processes. The organization's strategic quality planning must be shared and understood by employees. For this purpose, continuous training for all employees is required to work with the sense of having the customer focus. Unless management is determined to work on communication to inform process with strong commitment as a top priority, any effort to introduce QMS in the organization will be short lived. Without the functioning of all elements in an interactive way, one could not implement QMS in the organizations.

We urged that the communication to inform process helps the top management deploy the strategic quality planning with the employee's training to manage processes and focus on customers. In this model, for the "communication to inform process", I would have put as an element that unites all the other elements, permitting feedback and regulation of phenomenon as the level of "quality awareness culture – explained in section below". By this, I include a regulation of levels of "certitudes/certainties" and "incertitudes/uncertainties" functions in the process of continuously adapting the QMS to changing needs. All the quality elements need to be articulated together in order to get the QM implemented. Usually, quality related projects often face hurdles like communication gaps among departments / groups / teams, lack of confidence of the people in the system, impression of time wastage, unwieldy documentation, and misconception of common quality vocabulary. For this reason, communication

to inform process provides all the quality elements as opportunities to interact, provide feedback, and facilitate change. I consider the above elements as fundamental parts to evaluate the strength of a QMS and to implement the model of QM presented in this thesis.

Several research issues have been explored to understand and study the QMI process in organizations including QM definition, QM standards (ISO 9001 standard presented in chapter four; CSV presented in chapter five), and quality elements for implementation. The coming section addresses the phases of QMI.

9.4 QM implementation phase in organizations

QM elements that are necessary for QM in the literature have been discussed in chapters two, three, four, five, six, seven and eight and summarized above. However, to successfully implement QM and to foster continuous development, our aim is to present a QM implementation model for industry. QM implementation has always been essential for the organizations' long term survival; however, it currently plays an even more crucial role in the organization's future to follow the rapid pace of the markets' evolution. To implement any management practice, researchers have different viewpoints. Few consider this process as a social construction with no significant difference in output [2], while other believe that it can improve efficiency and allow organizations to improve products [73]. Failure to implement QM practices remains the major barrier to seek the benefits of the QM [194] [267]. But more importantly, planned implementation of QM helps to increase the ease of information sharing within the organization [135]. Information sharing is imperative for the QM implementation success with the help of communication to inform process, which is the ability to inform and communicate to employees the kind of changes the organization will cause to each employee responsibilities and tasks to create a culture of quality awareness. The whole process plays an important role in accompanying employees towards an improved understanding of the QM of the organization. The more regular and open the process of communication is, the better the awareness of quality is likely to develop between quality and other departments. Communication is crucial for developing a shared vision and a common understanding of organization's quality objectives. We

argued for a systematic quality approach, requiring the engagement and involvement of all employees in the QM implementation for which communication remained the pivotal process for informing teams and to engage them in the QM activities.

Our QMI model is based on the necessary steps required for QM implementation in industry. We consider QMI through some industrial cases presented in this thesis and by developing them with the help of the literature survey. The model of QMI resides under the umbrella of quality awareness culture. The quality awareness culture involves all the resources within an organization working together to make the system operational and paves the way for continuous improvements. The quality awareness culture is a philosophy that creates an attitude in people, affects the organization culture, and covers all the elements of quality system to develop a culture of quality awareness. It stresses the constant interaction among people, top management and processes necessary for the relations between the organizational efficiency and information and communication aspects. We now describe the concept of quality awareness culture.

9.4.1 What is quality awareness culture?

It means creating a common culture of quality in the organization. The major objective is to participate together in quality activities by sharing resources and knowledge at the right time. Quality awareness culture is the shared vision of a quality system for everybody in the organization when it becomes part of the organizations grassroot culture. This notion of quality awareness culture implies that changing the way people do their jobs – routine activities in organizations. In other words changing the way they do their job when ignoring or neglecting the quality procedures or norms defined by their organizations. It is the starting point for leading towards the quality awareness culture by altering the existing culture of organization. As discussed in chapter two and three and demonstrated in the case studies chapters (refer to chapter six, seven and eight), quality awareness culture change is a result of changing tangible features of organization which are described and identified as quality elements in this chapter. In these changed initiative efforts, when quality departments or teams are focusing on procedures

and associated actions for implementation, it is important to understand that it is their working culture that they are changing. Quality awareness culture interplays with the change efforts that gradually influence employees towards QM by implementation. This means that one needs to provide a fair understanding of the basic quality aspects for all the people who need to perform their functions and to prevent them from following inappropriate ways. As we have explained in first case study (chapter six), it was noticed that at the engine assembly line, at the time of audit, several quality problems exist, for example: job element sheets were not signed and updated, unidentified material was found at various places, SPC (statistical process control) sheets were not properly filled and signed, outdated, including deviation without proper counter measures, calibration stickers missing or unreadable, etc. These quality problems can be avoided with the help of quality awareness culture by involving people in the QMS and helping them to do their job in the required way. This helps them to apply quality standards. It is a challenging task to involve everybody in the quality system for several reasons (time, integration, coordination, adaptation, everyday practices/habits, dysfunctional certitudes, uncertainties, participation, commitment, patience, long term planning, etc). In terms of managing quality issues, the key aspect is to involve people in the quality process and empowering them to actively participate. One approach that is helpful in this regard is to generate short-term goals that can be achieved easily in visible periods of time [191]. We have provided examples in case study section (chapter six, seven and eight) that timely training is an essential element in QM implementation. Training sessions were held on quality tools (SPC, 5S, material identification and traceability in case study one; computerized system validation training in case study two and quality maintenance tools trainings on FMECA and CMMS in case study three) with the aim of engaging all employees in implementing QMS. Results from these case studies revealed that an appropriate training on quality was a prerequisite for successful implementation of QMS, yet the case study departments did not confront the issue due to the amount of effort needed for arranging and providing this training. In QM implementation, both quality and job related training is equally important. The major objective of quality training is to provide an understanding of the basics of the quality management deployment and increase employee's willingness to participate in the quality change, that is to say a change in their working culture. By job related training,

employees are directed and accompanied to plan their daily activities and working methods and to be able to work with responsibility. This training helps to contribute the quality awareness culture by supporting employees in involving QM activities. This in turn defines how to interact with all key actors of QM for implementation. As we have seen in case study one (chapter six), all team members were given an opportunity to discuss their due role on the engine assembly line that enabled team members to understand and implement their role. Once team members understood their role and the importance of QM, they came with suggestions to improve the working environment and their jobs. As indicated in case study three, cooperation among teams of different departments plays a major role in informing to communicate the shared tasks that can guide employee behavior in implementation of QM in an organization. We focused on increasing the cooperation among all departments working with maintenance teams to support QM activities, which in turn, affects the shared vision of departments (*i.e.* the VIT, the LDG, the POD and the ETO departments with the Maintenance department).

Top management is not meant to provide only quality tools but to strongly encourage people to actively use those quality tools for process management. As demonstrated in case study one where quality tools (SPC charts, calibration, etc) were not in regular use and thus little possibility of change for the quest of improvement was visible at the time of audit. Employees were not following the process according to what the QMS procedures required to maintain the quality system. After training sessions were provided and awareness of employees about QM was developed which was found helpful to properly implement QM tools. Top management plays in ensuring the success of QM implementation, because it is the top management's responsibility to create and communicate a vision to move the organization toward continuous improvement. We have seen that all improvement plans we found and proposed were strongly supported by top management to be implemented. As a result, we were able to create and sustain changes as needed to improve weaker areas. Top management employing this approach must recognize that trust and participation of people provide the power to understand quality issues. What is also incurred from the above discussion is that implementation of QM and quality awareness culture may be a thorny issue if communication is used without informing and without appropriate training.

9.4.2 Why organizations need quality awareness culture?

To answer the question, we have to consider the total cost of doing things wrong, the cost involved for all non-quality issues, the time spent to cover all negative effects, extra reports, etc. All these things are termed to be inefficient or cost to quality [144]. The top management is held responsible for strategic planning and foreseeing problems about wastes of manpower, materials, and machine-time, which raise the manufacturing cost. We have demonstrated in chapter six that failing to focus on the QM ultimate goal can create problems for organization in terms of implementation and only procedures, or quality tools without quality awareness are no substitute for making the QM successful. This meant that employees must learn to rely on learning and awareness to rely on QM standards to ensure that the customers obtain the product resembling that was described in quality procedures. Same quality problems were mentioned in case study three about the utilization of CMMS and FMECA approaches where employees were not fully aware of the importance of these quality tools for use in everyday life. All these quality problems like data sheet not properly filled-in and signed, outdated, process deviation without proper counter measures, documentation not controlled, etc are stimulated by lack of attention and knowledge for which training and self commitment are indispensable [75]. It is always cheaper to do the job right the first time [76] and timely training can prevent defects rather than after inspection to remove defects. The measurement of quality is the price of non-conformance [75]. On the contrary, quality awareness culture can increase and assure trust in the system (integration and adaptation) and to improve contribution from everybody (establish an improved QMI and culture which stimulates growth and competitiveness, to enhance teamwork) and improved communication-to-inform process. The basic purpose of quality awareness is to compile team experiences and communicate them to management for present and future improvement.

QMI fosters planning and focuses on human efforts; failure to achieve planned results indicates a failure in the quality process. Management must identify and correct such errors. It is assumed that people are the most important

element of the entire system [161]. Without the support of everyone involved in the team, no part of the system can work. No matter, how innovative processes and latest technology may be, for example, if the team members are not fully utilizing the system, or are not aware of strategic planning or do not follow the rules, the entire system will collapse. As found from case study one, two and three where employees were not aware of strategic quality planning, they not able to actively participate and follow the QM procedures. In all improvement plans, for example, in case study three, we stressed that strategic quality planning must be applied in all PDL teams in order to provide all the features of QM policies. For this purpose, continuous training and communication to inform process was proposed for all employees that improved the QM practices. Seventeen training actions were launched for three departments working with PDL department. In addition, the communication process was launched in parallel to ensure that all the actors were well informed about QM activities.

The case studies presented in chapter six, seven and eight refers to the development of an organizational QM system that improves learning to ensure the appropriate implementation of QM practices. The QMS is then guided towards continuous improvement of processes as well as to employee awareness which is important for a quality culture development, and finally for the organization's endurance. A quality awareness culture deals with people that make the system run. Many researchers have focused more on the technical performance of QM than the institutional consequences of adopting quality practices [379]. This deficiency has been addressed by using two complementary approaches in analyzing the QM role through processes of external adaptation and internal integration [198]. Some researchers considered this phase as the installation phase [263]. Some researchers used the term "sense making" to define the process of creating situation awareness in situations of uncertainty [375]. We use a blend of these concepts (quality integration, everyday use and quality system evaluation) to merge in our quality awareness culture concept. Thus three phases are necessary in order to develop a cooperative atmosphere where quality awareness culture binds QMS.

9.4.3 Phases of quality awareness culture

The QMI phases propose a set of practices for the implementation framework. These phases are summarized below.

- 1- Quality integration
- 2- Quality in everyday use
- 3- Quality system evaluation

9.4.3.1 Quality integration

Integration is customizing the norms with the organization's existing practices [89]. Quality integration is dedication to work which conforms to the QMS based on an analysis of the organization's existing internal processes. Integration can be described as lateral communication that spans divisions, functions, or departments. Integration can be accomplished through a number of mechanisms including cross-functional committees, liaison personnel, and task forces and finally, formalization denotes to written communications and standards. [132]. Lundby et al. (1999) uses the concept of total quality integration as it relates to the strength of quality culture [223]. They refer to "the extent to which the principles and philosophy of QM are fully integrated with organizations' culture". They claim that a QM based organization may create a strong, strategic and adaptive culture, which ensures the organization's long-term survival. The organization culture is invented, discovered, or developed by a given group as it learns to cope with its problems of external adaptation and internal integration - that has worked well enough to be considered valid and, therefore, to be taught to new members as the correct way to perceive, think, and feel in relation to those problems'' [403]. As we have seen in case study three (chapter eight), suggestion system was introduced in the department that enabled team members to propose and implement their suggestions in a way that could not be accomplished by organizations without such environment of awareness about QM. Employees who agree to work collaboratively to create ideas and test improvement suggestions in their organization tend to generate better solutions than existing ones. Creating a

partnership with customer and supplier departments - such as the ETO and the LDG in case study three through regular exchange of communication to inform the quality attributes - has proven improved results in QM activities. To improve quality awareness culture, it is important to understand the needs and perspectives of all constituents of QM and to support employees for engagement of associated activities and commitment of top management. Organizational integration also affects quality integration. According to Kim “Organizational integration revolves around the degree to which individuals receive information about the immediate job environment. It involves the degree of satisfaction with information about departmental plans, the requirements of their jobs, and some personnel news” [192].

All QM practices rely heavily on its influence on the core elements (*i.e.* QM elements define in section 9.2). Through this implementation phase [267] [268], we attempt to consider the management standard in situ which assures an organization to assimilate a QMS. The assimilation involves all processes set in motion to follow the desired practice. Thus quality integration means employees are involved in a quality process by understanding the system, procedure and operational environment. Employees develop the sense of adapting the quality standards that are provided in the forms of policies, instructions and manual. In the first, second and third case studies, we addressed the importance of QM standards proposed to all employees in the form of SOPs. In the first case study, team members were found working on the engine assembly line without respecting the standard working procedures. All relevant SOPs were discussed with employees in order to make them aware about the standard procedure to perform the job. In addition, they were involved to improve the procedure whenever possible. The step was an effort towards quality integration of all employees in the QM. Same case was seen in the case study three where maintenance team members were informed and trained on CMMS working process and the new SOP was finalized. Through this way, employees can be motivated to coordinate with quality standards and define their responsibilities for all quality actions and involve themselves in associated quality operations. The quality integration process calls for coordination with organizational culture to maintain a fruitful relationship between the two. Integration involves the recognition of stakeholder’s needs to produce

mutual agreement and common understanding of organizational goals and efforts. Thus, quality integration is the synchronization of organizational and quality needs and the expectation of stakeholders.

Common language and quality vocabulary create a mutual framework in viewing the operations and purpose of the organization. In the first case study, the quality triangle definition (policies, standards and guidelines, and procedures) was communicated to all employees of the engine assembly line and two training sessions were conducted to make the quality definitions clear for the blue collars posts. The same case was for the third case study where before deploying FMECA approach, all participants were provided with necessary definitions. Once these definitions were understood by the QM actors, the use of quality tools was easy to use and deploy for improvement. In the second case study, the CSV (computerized system validation) processes were explained to all IS employees in the form of training sessions which were held separately for each team. Thirteen teams head were given briefing to all CSV definitions and written material was distributed for all employees to familiarize with CSV terms. After individual team training session, a session for all IS teams was held together again. Whenever, an IS team member participated in the validation of a new computerized system, a CSV general presentation and documentation was given again to recall all notions about CSV. These three case studies explained that the shared view of the QM concepts is vital for employees' participation in quality activities and employee training and learning should focus on the quality issues. Common language is helpful in developing a shared vision of the QM activities in the organization. This expands the interaction roots in all departments to communicate successfully and respond to specific information in the same fashion [127]. Collaboration of the above factors provides an opportunity to enhance the capacity of quality integration. It should be supported by the PDCA cycle and continuous improvement principle. In addition, the structure of ISO 9004 for continuous improvement is built around this concept.

Naveh (2005) [263] wrote whenever any new practice (e.g. ISO standard) is brought in, there is a need to find a fit between the new rules and its old working habits of operating in the organization [242] as old working habits characterize past knowledge which was employed to cope with previous requirements [231].

The internal audits findings of the engine assembly line identified non-conformities which were related to deviation in working habits of employees *i.e.* JES (job element sheets) were not signed and updated, unidentified material was found at various places, SPC charts were not properly filled and signed, out dated, calibration stickers missing or unreadable. There was a need to conform working habits of employees in accordance with quality procedures. For this purpose, regular audits, training on all non-conform points were provided to apply standardized process for all employees. In various cases, the implementation of new practices seems to be sensitive as assimilation requires dynamic balance between the new practice and existing practices [45]. In case study three, 109 actions were proposed with the help of quality tools to improve the QM activities. Among others, actions were identified to replace current activities with new activities or to introduce new activity in the PDL department. To implement these actions, the responsible team members asked for a long implementation period (six months to one year). It was to adjust the existing or old practice or procedures with new one and to make sure that all concerned team members were able to participate in those actions *i.e.* preventive maintenance of computer system of equipments of test centre was proposed which was not accepted by other team members at once because they were not familiar with this activity before. Even after the implementation, they were guided again to integrate these activities in their routine job. Thus, we identify quality integration as a phase of the QM implementation and lead to the statement: **Less the quality integration phase accompanies a QM standard, less the problem of the QM implementation is solved.**

9.4.3.2 Quality in everyday use

In recent years, internationalization, severe competition, the improvement of communication flows, and the rapid transfer of technology are widely spread characteristics in most competitive environments. Quality integration is an important factor that seeks its application in the form of usage in everyday professional life. Implementation is not sufficient if an organization is looking for long-term effect on performance [267]. The everyday utilization of quality means that everything formalized and approved in procedures is applicable to daily routines, thus no need to hurry for the last minutes to prepare for external audits.

Without long and special prior preparation, employees can do what is required [344]. Askey and Dale (1994) state that the problem appears when managers took ISO certification as an end in itself, not as a means to an end, and that after certification they reverted to old practices rather than to maintaining the system [20]. Thus if employees just work for the audit then it means that the system existed but is not meant to be used in everyday life. All the QM audits for ISO 9001 certification require detailed and complete documented procedures and proper records, internal audit reports, control of nonconforming products, corrective and preventive actions to satisfy customers. We focused on the non-conformities identified during our internal audits which were held in the first case study to prepare teams for ISO 9001 certification. The objective of our audit was to ensure that all procedures were respected and followed. The phase of everyday use was not possible without the integration of employees in the QM which remained the first step. The quality integration supports the employees to understand, perceive and assimilate the QM requirements. However, the everyday use is the engagement of the employee to exercise the QM procedures, policies and activities to manage the process. In the first case study, we followed both steps (quality integration and everyday use) to implement the QM standards. Everyday use of QM activities can ensure that all established documented procedures are in use and the evaluation phase determines the level of implementation of QM activities in the organization. Thus the implemented system with quality integration should be used in everyday activities in order to remain conform to the applicable standards. Naveh (2005) wrote that everyday practice is regular application of a norm or standard [117] [107] in a pertinent way that it becomes part of an organization's everyday routines [74] [263].

Identification of improvement should be the result of quality practices in everyday routine otherwise daily routine will remain distant from producing quality results [178]. Communication seems to play a critical role in this process. The case study three explained the role of communication-to-inform process among the different PDL departments. The desired information of all relevant departments (VIT, LDG, ETO and POD – refer to section 8.9.5 for details) was found essential to be communicated in improvement actions. Increased cooperation through exchange meetings among these departments and provision of KPI to

justify the propositions were helpful in understanding each department's participation and difficulties facing to achieve the quality targets. All improvement actions were basically the start of the aim to improve the communication of maintenance management inside the PDL departments. Moreover, communication-to-inform process helped team members to increase participation after having a better perception of quality tools. As a result, CMMS tool utilization was improved in the year as explained by the maintenance manager.

The change process that includes integration, daily usage and identification of improvements is required to be fully exposed and all employees need to know why they are expected to be a part of this process [180]. As in first case study, we observed that employees were not aware of the QM utilization because they were not integrated to QM standard (*i.e.* ISO 9001). We focused on explaining to employees why the respect of QM standards was necessary. I remained involve with all employees of engine assembly line to inform them clear standards for acceptable work, and provide the ways to achieve it (details are presented in section 6.6 and section 8.9). When organizational change occurs, people must acquire many new concepts that must fit together into a comprehensible whole [189]. The case studies emphasized that the organizations function through a series of specialized activities carried out by different departments. Each department in the QM was responsible to carry out its assigned quality activities and also to share the responsibility of managing the change process to improve the weaker areas. The everyday use involves activities that, if carried out on continuous basis, will result in improvements in quality and will eventually result in unprecedented performance that will help the organization implementing QM.

Organizational changes that enhance the horizontal flow of information and empower employees to make decisions are critical to gaining the benefits of any innovation or change [400]. These communication problems can lead to ill feelings and even to division [38], which may cause environment of confusion, misunderstanding and conflicts. The case study three revealed that there was a need for the maintenance department to increase the communication with other PDL departments to reduce about 6 % of the production losses. In 4 % of work orders in 2005, it was observed that the due reason was the lack of cooperation between the LDG department and the maintenance department. Same case was

observed for the ETO and the VIT department. The improvement actions proposed later to solve these problems were viewed in the form of communication-to-inform process which was helpful to plan, direct, inform, persuade and control their operations in the PDL departments. Communication to inform process allowed these teams for planned communication on regular basis to timely exchange information, rapid feedback and timely closure of the issues discussed in their meetings.

In case three, I worked on QM improvement for which I had gone through maintenance management problems for 2005-2007. I focused on periodic problems via CMMS (computerized maintenance management system) to propose solutions, the recurrent problems through FMECA approach to get the detailed explanation of the equipment under observation for quality maintenance improvements. Both QM tools provided a forum for communication of organizational maintenance management strategy, and appropriate training was found necessary and provided to all employees to perform work according to the requirements of QM. The QM tool adequate utilization requires an excellent integration among people, machines and information, building the QM system that excels to quality. The identification process for improvement can and should become a starting point for innovating the paths an organization can do business and a focal point for continuous improvements. To summarize, the phase of everyday use of quality seems to need an effective construct to help employees successfully carry out the required tasks in the dynamic, continuously changing business environment. Quality in everyday use is the element that helps overcome the implementation obstacles and that offers guidance to all employees. Thus, we identify quality everyday use as a phase of the QM implementation and lead to the statement: **Less the QMS everyday use phase accompanies a QM standard, less the problem of the QM implementation is solved.**

9.4.3.3 Quality system evaluation

Quality integration and daily utilization are critical steps, however, not enough to fully implement QM. Another important step which leads to measure the potential of the system is by evaluating it in terms of organizational goals. Evaluation helps to monitor the satisfaction of interested parties. Evaluation is a

sort of measurement that provides the starting point by offering an understanding of quality parameters, relevant issues that require focus on progress [177]. Measurement is the barometer that is helpful in distinguishing the difference between actual performance and the stated goal [402].

An evaluation of the existing QM practices of the case study organizations (presented in chapter six, seven and eight) was done to measure the satisfaction level of the deployed QM. These organizations were found willing to measure the difference between the actual performance and the desired goal to improve the existing system. Several tools were used to make an evaluation (*i.e.* in first case study by internal audits; in second case study by external audits of regulatory authorities; in case study three by quality tools data) to measure the room for quality improvement and implementation of QM. The weaker areas identified during evaluation helped the organization's QMS conformance to written QMS but also improved the organizational performance. It was discussed already in chapter six that training for employees on different QM activities is a prerequisite to implement the QM in the organization. One of the findings in all the three case studies was that, there is no replacement of training for the QM implementation and there is a clear need for continuous, timely and appropriate training. According to the evaluation results of case study one and three, there was a need of training actions for carrying out changes in the existing operational activities. The existing understanding of team members was not comprehensive and did not integrate different quality tools and methods to improve the existing QMS. For all these case study organizations, a major improvement action plan was training of the employees on QM tools and procedures to follow the quality activities.

Once an evaluation report is established, and improvement plans to remove non-conformities and weaker areas are identified then an organization needs to maintain all the quality activities currently being done to ensure that it is appropriate both in design and use. All quality standard documents (quality manual, procedures, work instructions, audits) can be useful in maintaining the system. As discussed in the previous paragraph, training is the vital element to introduce all quality standard documents in any department. Our study (chapter six, seven and eight) reveals that without appropriate training, employees cannot be engaged in using these quality standard documents in everyday life and to use

as a catalyst for change. The training on timely and continuous basis helps employees to remain on the track of QM implementation (refer to section 6.5, 7.11 and 8.8). This leads to a quality improvement phase involving the application of QM practices to all aspects of the business. QMS must be employed through out the organization and at every level after evaluation on regular basis as we conducted for case study organizations.

Evaluation is the only instrument that assists the measure of the satisfaction level of organizational specification. Evaluation and decision-making at all levels of the organization need to be supported by a communication-to-inform process to improve quality performance [300]. Evaluating the situation in an organization's QM practices provides an important base for the organization to improve its QM practices. In case study three, we started doing work by analyzing the existing situation to identify room for improvements. This evaluation process was taken as an assessment to measure the difference between actual performance and the desired one. Then the focus was to reduce weaker areas impacts and elimination of possible production loss by formulation of improvement actions. The reduction in 3 % of production loss demonstrated that the evaluation plan led to some sort of improvement. In addition, cooperation among different department was not possible without evaluating its need.

Evaluation is the key dimension for continuous improvement because it emphasizes incremental changes, which can generate an organizational climate to measure its achieved goals. This phenomenon would be reinforced by the interest in avoiding failures and in doing things well, which would induce certain risk aversion associated with the trial and error processes crucial in any change process. During this stage, organizations began to emphasize on the importance of satisfying the needs of customers, both internal and external. Under evaluation phase, employees are asked not only to participate in decision making; they are empowered to make their own decisions as shown in case study one (refer to 6.5.3). Thus we identify quality system evaluation as a phase of the QM implementation. This allows us to state: **Less the QMS evaluation phase accompanies a QM standard, less the problem of the QM implementation is solved.**

In the literature survey and case studies presented in this thesis, the quality elements and implementation were explored. In addition to literature surveys, my discussions with quality practitioners in the case studies in the industry and international conferences (appendix 4) has also been an important source of information to concentrate on QM implementation in organizations. One of the findings was that, there are no unique existing standards for quality management on which there was consensus of practitioners and researchers of QM. During the last six years of studying the subject of QM, I did not come across any constructs especially designed for implementing QM. Consequently, the answer to our research objective can be proposed in the light of our case studies. We have provided three case studies with various improvement plans. We identified three phases of QMI and made these observations to develop a model for QMI to facilitate organizations to plan and implement QM standards.

9.5 Model Formulation for QMI phases

Based on the above three hypotheses, a model of QMI was developed and is presented in *Figure 9-1*. The three boxes are representing the phases for QMI phases through a quality awareness culture. In this model, three boxes (quality integration, quality everyday use and quality evaluation) are regarded to develop a quality awareness culture necessary for QMI. It should be noted that all these QMI phases are linked by a communication-to-inform process necessary to implement each phase in organizations. Implementation of QMS is dependent on how the QMI phases are articulated according to the mentioned phases. To the best of the author's knowledge, no researcher has proposed such a model in studying the comprehension process of implementation phases in the industry with QMI.

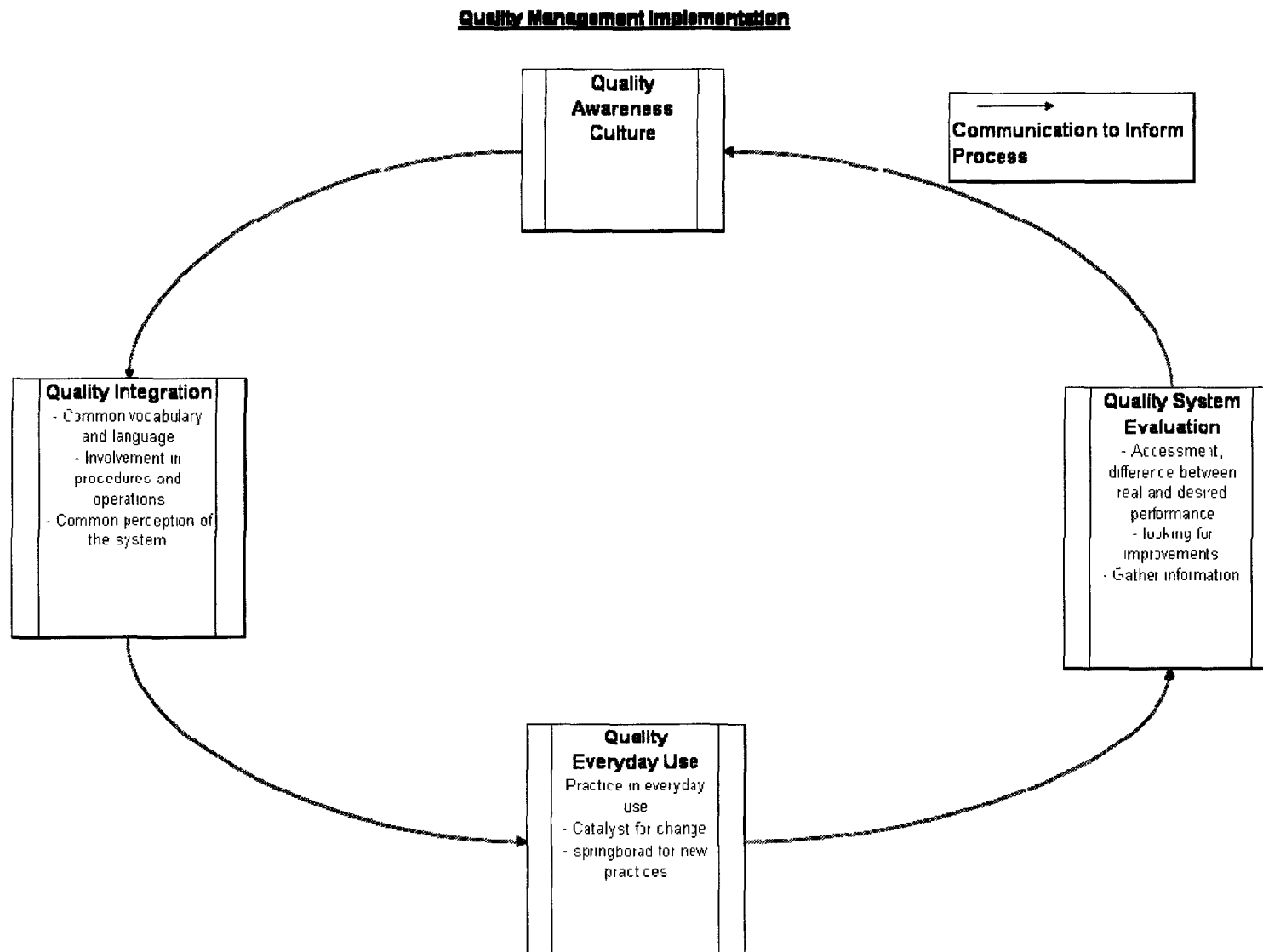


Figure 9-2 : Implementation phases of quality awareness culture in an organizational QMS

Like our first model of QM elements (refer to *Figure 9-1*), we have demonstrated that communication-to-inform process facilitates the quality integration phase for deploying the quality everyday use phase for all employees to maintain the QMI case study organizations. The continuous evaluation phase of quality system consists of an attempt to ensure that organizational members are able to understand and implement QM and to find the areas of improvement to develop a quality awareness culture. In this model, quality awareness culture is developed by maintaining the “quality integration, quality everyday use and quality evaluation”. Then, these phases are supported by “communication to inform process” throughout the QMI process. We have presented in our case studies and in this section that communication to inform process is a central aspect of how a QMS is implemented. It is important in quality integration phase and everyday use to align various quality elements (refer to *Figure 9-1*) in the organization. One of the key phases in QMI is the explicit identification of processes and tasks, they are diffused in the organization through employee’s training, which leads to a common perception of the QMS. Quality everyday use is dependant on engagement of employees with the organizational QMS and “communicate to inform process” to perform the change process. The evaluation phase is based on the analysis of existing QM activities to continuously improve organizational QMS.

These three phases (quality integration, quality everyday use and quality evaluation) are grouped around quality elements and indicate the quality awareness culture of an organization and QMI level. Now we present the combination of quality elements and quality awareness culture in the single model to provide the understanding of implementation of the QM in organizations with the help of *Figure 9-1* and *Figure 9-2*.

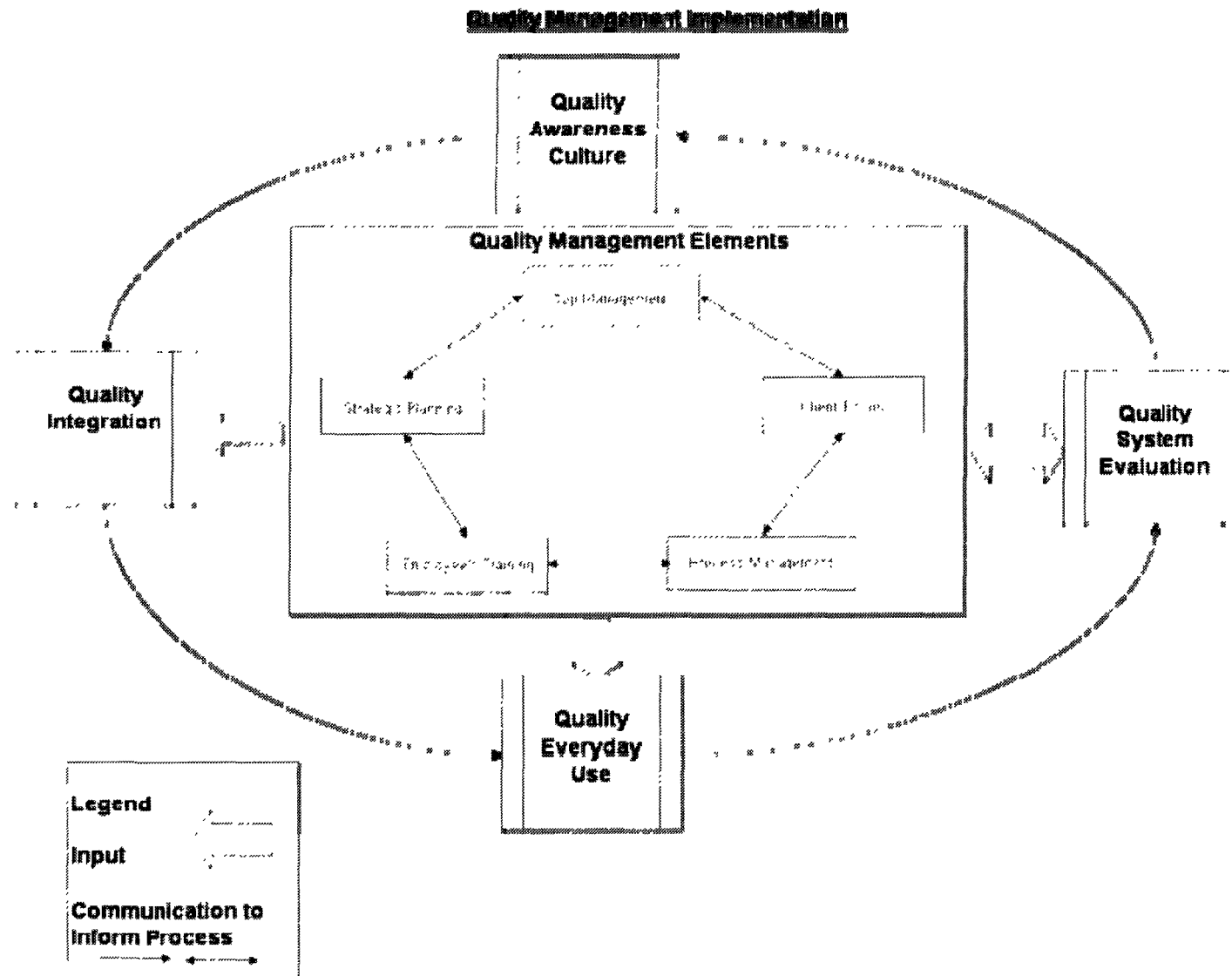


Figure 9-3 : Model of QM elements and QM implementation by quality awareness culture in organizations

In this model (*Figure 9-3*), an organization is free to select a QM necessary to meet the major objectives, which are linked to three phases of the quality awareness culture. The major elements of QM are described in the inner box (top management, strategic quality planning, employee's training, process management, customer focus) surrounded by the quality awareness culture to implement QM. All the quality elements are considered as an input for quality integration phase, quality everyday use phase and quality evaluation system phase. It should be noted that quality evaluation system provides the input to QM elements in the form of improvement plans (refer to section 6.6, 7.5 and 8.9 for details). The evaluation phase can help organizations to distinguish weak and strong areas of the organization's quality awareness culture. With the help of evaluation, one can determine the quality awareness culture to improve quality integration and everyday phase. Keeping in view this point, it is considered that stronger the degree of quality awareness culture has, more it contributes to successful implementation of QM. The major part of a literature survey and the case studies in this thesis have focused on the identification of these quality elements (*Figure 9-1*) and QM implementation phases (*Figure 9-2*) and in analyzing how they can be used in the quality awareness culture (*Figure 9-3*). An organization is required to have a communication to inform process to support all its QM elements and QMI phases for a quality awareness culture. The basis of each quality element and QMI phases brings forward some explanations as to why they are part of quality awareness culture. This examination is done for each quality element in case studies (chapter six, seven and eight) and is based on the implementation of QM in our case studies organizations. The phases of QMI and quality elements are a result of a quality awareness culture in the automobile and pharmaceutical industries. It was created as a tool for QMI. In order to adapt the QMI phases and to evaluate the effectiveness of QM elements, an organization must create a shared understanding among the actors of the QMS. It has an effect on how the organization informs through communication what the standard is and how it is used in the organization to manage quality matters. According to our studies, communication occupies a central role in the process of quality integration and aligning the QM elements for everyday use. The dominating information from quality system evaluation is assumed to be used a basis for improvement process for QM awareness culture. In this evaluation phase, the organization is expected to

scan the QM elements and measure the QMI phases in order to gain information that is analyzed and communicated for the development of a quality awareness culture.

Based on the above discussion, a model of QM elements and QM implementation was developed, and is displayed in *Figure 9-3*. The links between QM elements and QM implementation through a quality awareness culture are integrated in the single model. To understand the effect of quality elements on QM implementation in industry, we proposed two major hypotheses based on the provided case studies findings and literature survey. Table 9-1 shows the list of hypotheses generated for this study. All these hypotheses were confirmed with the case studies presented in this thesis (refer to section 6.4, 6.5, 7.10, 7.11, 8.7 and 8.8).

Hypotheses	
H1	Less a QMS is accompanied by these six QM elements, less the problem of the QM implementation is solved.
H 1a	Less the QMS is accompanied by top management , less the problem of the QM implementation is solved.
H 1b	Less the QMS is accompanied by employee's learning , less the problem of the QM implementation is solved.
H 1c	Less the QMS is accompanied by customer focus , less the problem of the QM implementation is solved.
H 1d	Less the QMS is accompanied by strategic quality planning , less the problem of the QM implementation is solved.
H 1e	Less the QMS is accompanied by process management , less the problem of the QM implementation is solved.
H 1f	Less the QMS is accompanied by communication-to-inform process , less the problem of the QM implementation is solved.

H 2	Less the phases of quality awareness culture accompany a QM standard, less the problem of the QM implementation is solved.
H 2a	Less the quality integration phase accompanies a QM standard, less the problem of the QM implementation is solved.
H 2b	Less the QMS everyday use phase accompanies a QM standard, less the problem of the QM implementation is solved.
H 2c	Less the QMS evaluation phase accompanies a QM standard, less the problem of the QM implementation is solved.

Table 9-1: List of Hypotheses

9.6 The Role of the QMI Model in this Study

The model proposed here after careful observation and understanding of three case studies provided some benefits for the organizations and QM at the beginning. It was an important aspect of the quality internal integration of the organization towards quality awareness culture development and had symbolic value in demonstrating these organizations' commitment to quality. We have demonstrated that QMI led to ISO 9001 certification, increased sharing of information and improved communication in departments to a minimum level. However, we found that there was a need of permanent communication to inform process in organizations at all level to integrate, develop and maintain the QM activities. There was a strong need for understanding and managing strategic quality planning through timely training for all employees. We found that employees took initiative on QM system when they were provided with quality tools and timely training. We urge that organizations need to invest in the development of the employees through preventive training on their QM system and related activities. Our approach of preventive training will be helpful for organizations to reduce costs of corrective activities after quality problems occurrence due to lack of training. It is always cheaper to carryout QM activities right the first time rather than after inspection. Our case studies revealed that failing to focus on the employee's training and communication to inform process to all key actors of QM system can create problems for an organization.

Our model of QMI provides ways for integrating the quality (development, maintenance and improvement) efforts of all departments in an organization so as to make quality activities visible for all employees. Moreover, the model presented in *Figure 9-3* provides an understanding about the interplay between quality awareness culture and communication-to-inform process for the purpose of QM implementation. The model presented in *Figure 9-3* has integrated two models in a single model. First, it provides interplay between quality elements and communication-to-inform process to develop a QM. Secondly, quality awareness culture is integrated to implement an organizational QM with the help of QMI phases. Here interplay between these phases and communication to inform process is presented to implement a QMS in organizations. It is important for organizations to implement a QMS in everyday life of employees. When people differ in their experience in everyday life, it usually causes tremendous communication problems [319]. From a QMI perspective, these phases (quality integration, everyday use and evaluation) related to organizational standards have significant implications in how QM standards should be managed and deployed. The model is suited for an organization conducting similar and repetitive quality projects at the operational level presented in case studies, but the models do not provide a final solution for managing QM in organizations. There is a need for additional research that would focus on the development of QMI practices and an awareness culture in these types of organizations.

An emphasis on employee's training for everyday use process to deploy strategic quality planning of QM and communication for information sharing across different team boundaries should be the main area where a strong quality awareness culture in the organizations is based on three basic phases. We identified these distinct phases the organization to develop a strong relationship with employees through the communication process. The major obstacle to overcome is the communication-**not**-to-inform process, which do not support the implementation of QM in organizations. An organization must develop means to maintain this communication to inform process throughout all phases of QMI.

9.6.1 Research considerations

This study has focused mainly on the understanding the role of a quality awareness culture and communication to uncover implementation phenomenon in organizations. This type of analysis may be useful for the practical understanding and development of the QMI. In this research it is proposed that QM should be studied as a cultural awareness phenomenon with the help of communication and information analysis. From this perspective, QMI is described as an organization having a quality awareness culture and a communication-to-inform process. The nature of the QM and communication discipline can provide the connection to other fields of academic research, but can also be used as a tool for studying the practical implementation and application of QM in organizations.

These research results demonstrate that quality awareness culture is based on a mutually compatible set of quality elements, a communication-to-inform process, which can be considered as a basis of QMI. As a specific field in organizational research, QMI should focus on research on communication as informational process in a quality awareness culture, where the type of environment would be able to support such a culture and consequences of mismatch between quality culture and communication process.

An assessment instrument was built up to measure the QM implementation and practices. This tool was based on the elements used in the model to evaluate and identify weaker areas. The instrument is actually the transformation of QM components, implementation practices into core activities. The assessment instrument is presented in appendix 5.

9.7 Contribution and assessment of this study

9.7.1 Contribution

The contribution and assessment of the study is usually based on two factors: importance of the field of study and special contribution of this study [198]. We have defined the research strategies for this study in chapter one. In this

type of semi-qualitative approach that we followed, the contribution of the study and validity of its results should be assessed by the scientific community as well as by QM specialists working in industry using these techniques. The thesis presents those insights that I have gained during my quality journey and I have presented a few issues, which I consider related to the assessment of this research. This research makes a contribution in the following areas:

- Clarification of the definition of communication to inform process in organizations and justification about its usage in QM.
- Role of communication in organizational quality awareness culture.
- Analysis of QMI process and role of communication in industry.
- Identification of the quality elements and their role in organizations.
- Identification of QMI phases and their role in organizations.
- Development of a QMI framework to analyze the role and impact of quality awareness culture in organizations.

9.7.2 Assessment

Like all studies, this research is not without weaknesses and limitations. This research is semi-qualitative in nature (refer to section 1.8 for details), and the determination of the validity and reliability of the results should be based on the criteria developed for research in scientific community. The primary focus of this research has been to create useful constructions for increasing our understanding of QMI and understanding the role of communication and how it can be applied in the organizations. In this study, various sources of data were used in different phases of the research including extensive literature reviews, experts, users, archives, international conferences, Internet, etc. Furthermore, in working in the industry, it provided an opportunity to observe the industries in a detailed manner and on a regular basis, thus, making it possible to measure, compare, evaluate and cross-check the consistency of information inferred at different occasions and by different sources and means. QM procedures and documents were reviewed after

various informal discussions and workshop sessions to compare with users and quality specialists' viewpoint on different occasions during the research phases. All this was done to cover a maximum number of things from the case study organizations and to point out similarities and differences in data by identifying various sources of explanation. However, in general, little emphasis has been placed on whether these frameworks and research results can be validated according to established scientific criteria of validity and reliability. This latter is recommended to be pursued in further studies by other researchers.

In all the case studies, the experience of QM was shared with external researchers working on QM. Mutual discussions with explanations of scenarios, observations of implementation process opened the door to different possibilities concerning the research findings to help compare different cases and consider possible interpretations. Various methods were considered in the data collection. QM of organizations were accessed and evaluated and available source of documentation was studied, weak areas were identified, improvement plans were developed and actions were proposed.

According to Yin, establishing a chain of evidence and events is defined as the extent to which the whole research process (from the research issue to the final conclusion supported by all the relevant evidence to examine the research questions in order to answer it) allows a reader to follow all the above processes to find conclusions and answers by reading the research report [397]. In conducting and presenting all the case studies, the chain of evidence was maintained by offering a structured pattern from questions to arrive at the conclusion with the help of proof. The research issue was extracted from the problem domain and the research questions were proposed. A research model was proposed to resolve the research problem and facilitate an improved understanding of the research issue.

9.7.3 Limitation of the study

It is important to view this study in the context of its limitations. First, data used to develop the model came from only three multinational organizations (*Toyota, Sanofi Aventis and Volvo AB*). Strictly speaking, the generalization is

limited as QM elements and implementation data were obtained from only three case studies. Thus, the data may not be very reliable and the research findings might have been unnecessarily biased. Moreover, the measure of perceived quality elements and implementation in particular is relatively weak, because it looks at the implementation of QM through, essentially, in-house evaluation reports, discussions and archives, and asked respondents for their general perceptions of overall environment in a limited time frame.

Using French and English to collect data caused some challenges concerning the reliability. For instance, using French may have caused some inaccuracies or even distortions that, in turn, have made it difficult to connect the original data with interpretations I have produced in all the case studies. Most of the discussions within the organizations were in French in which I did not possess an excellent command, thus leading towards some barrier towards an over rapid communication in terms of vocabulary. However, this seems to be an advantage while working with workers who often discussed frankly when meetings were evoked. However, I tried my best in collecting, analyzing and interpreting the data and made all possible efforts to prevent inaccuracies from occurring in those phases of the research to reduce the impact of this factor.

9.8 Summary

The chapter first presented the research strategies adopted for the study through a literature review (presented in chapters one, two, three, four and five), and case studies (chapters six, seven and eight). In this way, the research strategies adopted in this study can be characterized as the combination of qualitative and quantitative strategies *i.e.* semi qualitative approach was used to develop the QMI model. An initial list of items describing six QM elements was generated from a review of communication in organizations and QM literature that included: top management, employee's training, strategic quality planning, process management, customer focus, communication-to-inform process. Case studies provided several notions about these elements. Afterwards, QM implementation phases were identified including quality integration, everyday use and quality system evaluation. Then, a model of the five quality elements with QM implementation phases was developed for quality awareness culture. The purpose was to ensure

appropriate coverage of each QM element in the model and interplay with communication to inform process. The aim of this model was to develop a QMI model for industry and understanding the role of communication for which communication to inform process was integrated with QMI. Thus, it was possible to empirically test the above model in industry. Contribution and assessment of this study was presented to demonstrate the importance, special contribution of this study and validity of the results presented.

Conclusion

Conclusion

This semi-qualitative research has provided an opportunity for understanding the QMI phenomenon in industrial environments and has described a basis for implementation in organizations. Three case studies demonstrate that our novel vision of QM implementation model can be used to evaluate the QM elements, implementation attempts phases and a quality awareness culture to observe organizations' continuous improvement actions and evaluate the improvements over time. It is concluded that our model can be helpful in promptly distinguishing the areas that need improvement and the quality level achieved by organizations through carefully using the available resources.

All organizations work in different ways according to their business nature, objective, background, technology use, market, people employed, etc. Thus, no general model exists and can be applied as a standard rule. Moreover, organizations use different models according to their requirement to implement QM that is based on their business needs. Thus, no organization is required to adopt the QMI model presented in this study in full but a suitable combination and blend with the organization's quality practices already adopted can lead to use its resources wisely. An organization's specific need always influences QMS, thus any synergy of an it's already developed QM model with our presented model can excel QMI in specific cases.

According to the presented theory and data in this study, the originality of our research is demonstrated by the combination of QMS and a culture of quality awareness. I tried to develop a clear structure for the QMS and made it practical for QM standards. Both, the construct's practical and theoretical input were thus applied in an organization's context. Quality specialists perceived that the proposed QMI model was a generic construct. It was developed after studying the QMI process in different industries and in different kinds of quality projects; that is, for carrying out engine assembly line operation, for improving team assimilation for quality, their attitude towards quality, computerized system validation and dealing with change management and file management (chapter five and seven). It was also demonstrated that the QMI model is comprehensive covering various phases of QM in organizations, includes ISO 9001 certification, a

CSV viewpoint and pays attention to distinctive features of organizations towards quality awareness for QMI (chapters six, seven and eight). Furthermore, the proposed model was found useful at an operative level of three different departments of organizations.

The discussion on the practical relevance of the problem domain was presented in chapter one. Further insights were later discussed particularly in chapters two, three, four and five. Chapters two and three provided a literature review study and provide a ground to observe and understand the QMI in industry. In addition, it supported the hypotheses that were demonstrated in the case studies chapters and later presented in chapter nine for a novel construct for QMI. Chapter nine, in particular, offered the model simulation, and linked the chapter with the model and affirmed the need for a novel construct. The practical relevance was explored in the three case studies.

The proposed model for QM can be connected to the existing theories in the problem domain as various constructs reflect the important issues and quality elements were carefully selected from QM and communication in organizations' literature and a possible application in case studies was proposed. All pertinent features of QMS were demonstrated in relevant industrial contexts in terms of organizational needs. The characteristics of the QM in industry were considered to support the model.

According to the presented case studies, the QM model was found useful in grassroots practice. It was further supported by various QM industrial approaches to evaluate the effect of the quality elements and implementation. Though I observed various factors and the quality implementation team point of view, efforts were focused on covering the issue in a large scale. The proposed model was found capable of corresponding to the QM need for effective implementation through a quality awareness approach, communication-to-inform process and continuous timely training for all actors of QMS.

The use of the proposed model had clearly some important effects on QM as it seeks to solve the problem of QMS in the various case studies. The provided dimensions were found vital for solving the problem of a system and its

implementation. At the very least, the proposed model was found useful in reducing QM problems in industry *i.e.* communication gaps among different teams, lack of the same perception of the quality system, misconception of common quality vocabulary, quality integration problems. Our models (refer to *Figure 9-1*, *Figure 9-2*, and *Figure 9-3*) integrate communication in QM elements and QMI process to inform and train employees about the QM requirements. Our quality awareness culture approach is incorporated in the model with communication to inform process that provides all the quality elements of the opportunities to interact, provide feedback, and facilitate change. We observed our QMI as an approach guided by quality values and principles for building and managing change in organizations. Quality teams can use and plan to observe the quality elements in existing and future quality projects, and in a clear way. Communication remains the glue to keep all elements together and for this reason, we considered that this element has a dominating role on other QM elements for reducing (Communication-to-inform process) or increasing (Communication-not-to-inform process) the problem of QM.

According to the provided results of the case studies, the originality of the research is visible. It is observed that the proposed construct and implementation model as a whole, have strong impact on industrial QMS and for this reason focus on issues like communication-to-inform process, evaluation - list, common vocabulary, participation of various working teams in documentation and workshops, training were emphasized in great detail for their importance. In this way, a practical approach was demonstrated to support the proposed theoretical constructs.

The research investigates the role of communication with quality elements, QMS implementation and a quality awareness culture development and reveals that there is no short cut for quality. However, within a limited time frame of implementation, any organization can achieve success by realigning its quality efforts to meet its business needs. QMI is not a mere technique, it is a cultural revolution, a way of life which results in a change for improvement. It means involving everyone – from top management to workers.

While concluding the findings of the studies presented in this study, it is to be mentioned that less the QMS is accompanied by quality dimensions, less the problem of QM implementation is solved. Thus, QM constructs affect the QM implementation phases. In addition, QM constructs and QM implementation are necessary for the development of a quality culture. After a review of the literature survey, and case studies, the phenomena of communication appear to be critical in driving the successful implementation of an organization. In a quality awareness culture there is a shared understanding about QM practices and, for example, quality department and top management are expected to provide a clear approach for implementing the QM standards. All quality tools require adequate and timely training before use. In addition, a continuous communication loop is required to inform employees about QM activities. QMI success is dependent on communication process established for QM to involve employees to provide and manage change.

Internationalization of markets, increased quality requirements, tough competition, and supplier pressure led to various visible moves for quality. These moves can be any of quality techniques (QM, Deming cycle, SDCA Cycle, TPM, Kaizen, Six Sigma, Computer System Validation, TQM, FMECA, SPC, Lean Management, JIT, 5S, Change Management, etc). These all require strong management commitment, time and resources in implementing a QMS. The need for promoting a quality culture will remain the backbone of all the quality systems. Regardless of which route industries take on their quality journey, these principles of QM can provide outstanding leverage for running world-class business. It has been observed from my experience over the past few years that the successful QM is based on working with people by involving them in all the possible steps. The QMI is a comprehensive approach that ensures the coherence between the organization's vision and the people working for it to formalize the QMI phases and quality elements.

When the real strength of the employees is recognized, as those who make the quality process function, organizations can enhance its culture towards continuous improvement through QMI. By pursuing all kinds of QM tools, quality manages and their sponsors may articulate a new assembly concept that is more meaningful and attractive to all especially for the blue collar employees. One can

get outstanding results from ordinary people by integrating them into a culture of quality awareness to manage the quality process. It is argued that I have experienced some organizations achieve modest results from brilliant people without providing them a culture of quality awareness to manage these processes for QMI. QM moves around through timely informed human beings.

Hence, a simple design of QM was found helpful in implementing QM standards along with proper co-ordination through timely information among teams, process and top management to implement strategy for QM. The case studies presented as examples of how to use this QMI model and quality elements for a better quality awareness. However, the ultimate success is linked with the understanding of an organization's QM according to the business needs. Since the process of QM is never-ending, thus, there is always the possibility of improvement. No doubt, the implementation process takes time that requires engagement of various resources and patience and a commitment to succeed.

Future research perspectives

The main focus has been on studying the role of communication and a model development for QMI. Some analysis into the quality awareness culture in organizations has been included in this thesis mainly to demonstrate the potential value of the framework in the analysis of practical problems in industry. The analysis of the role of communication in a QMI process must be further examined in future in broad context by multiple case studies. A similar approach can be used to analyze the potential use of a quality awareness culture development in other industries. The research methodology and conceptual framework should also be applicable in studying other QM practices and standards. This research could be extended by the application of this framework to another organization that may be based on non-industrial sectors.

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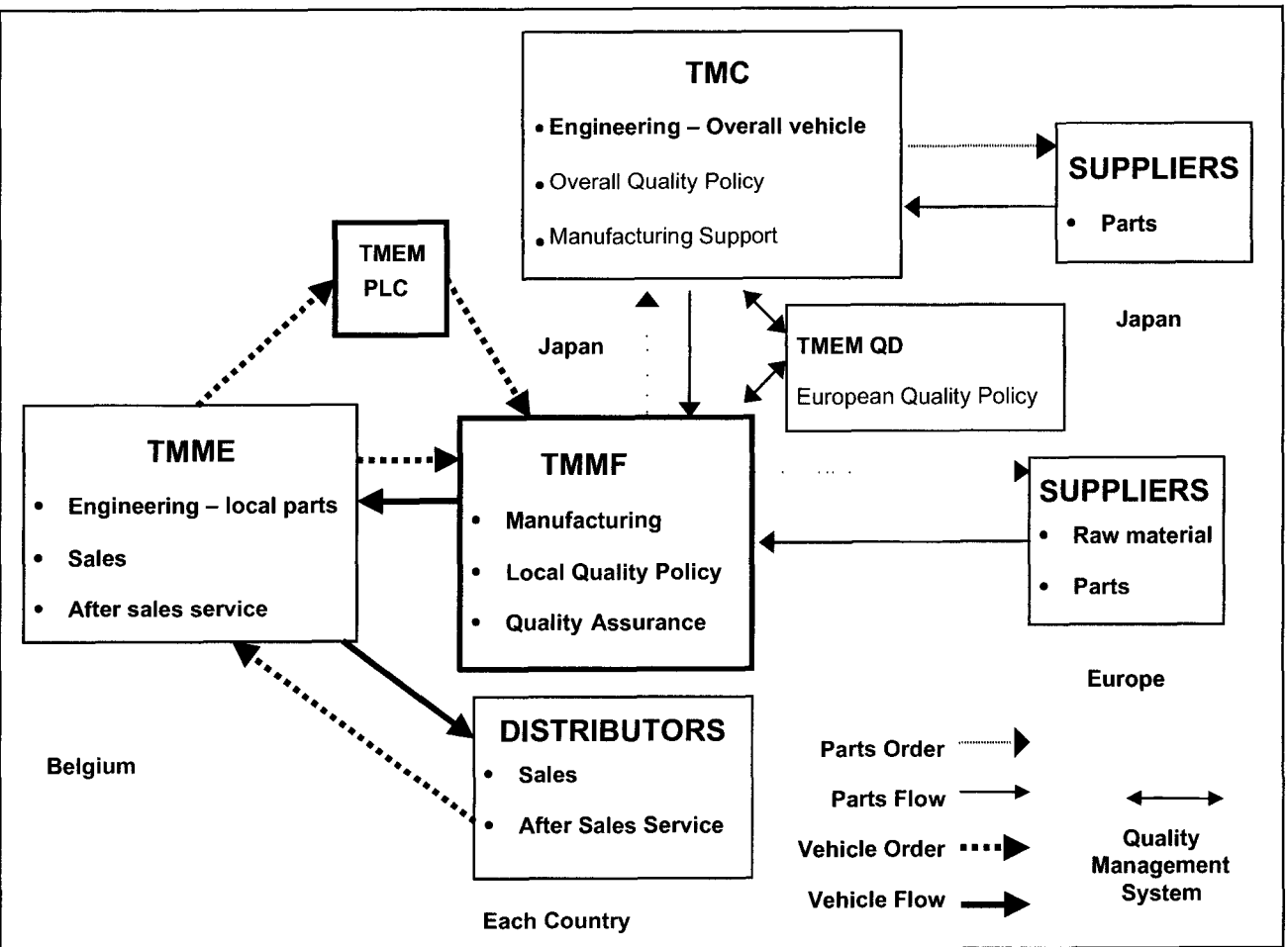
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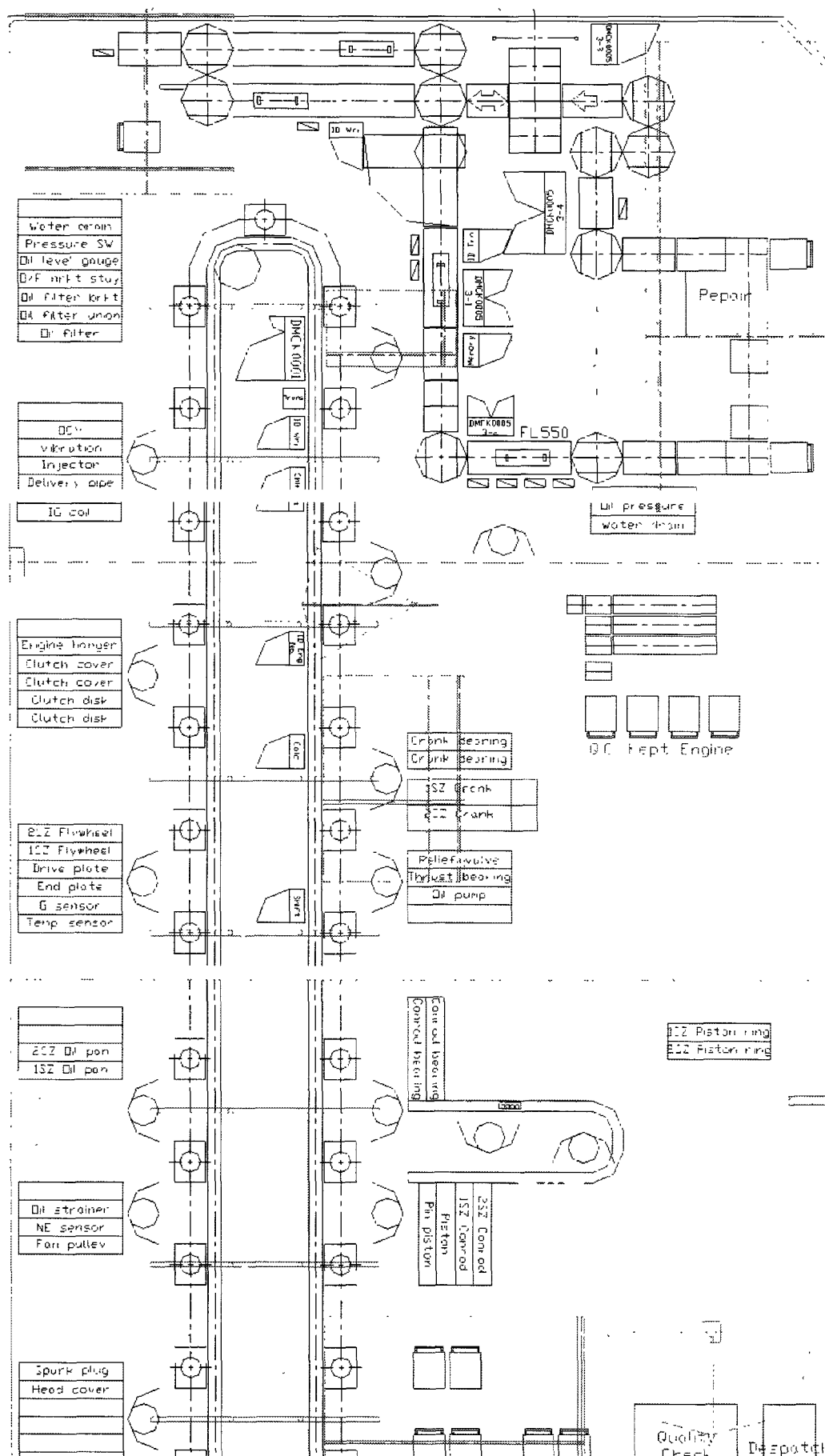
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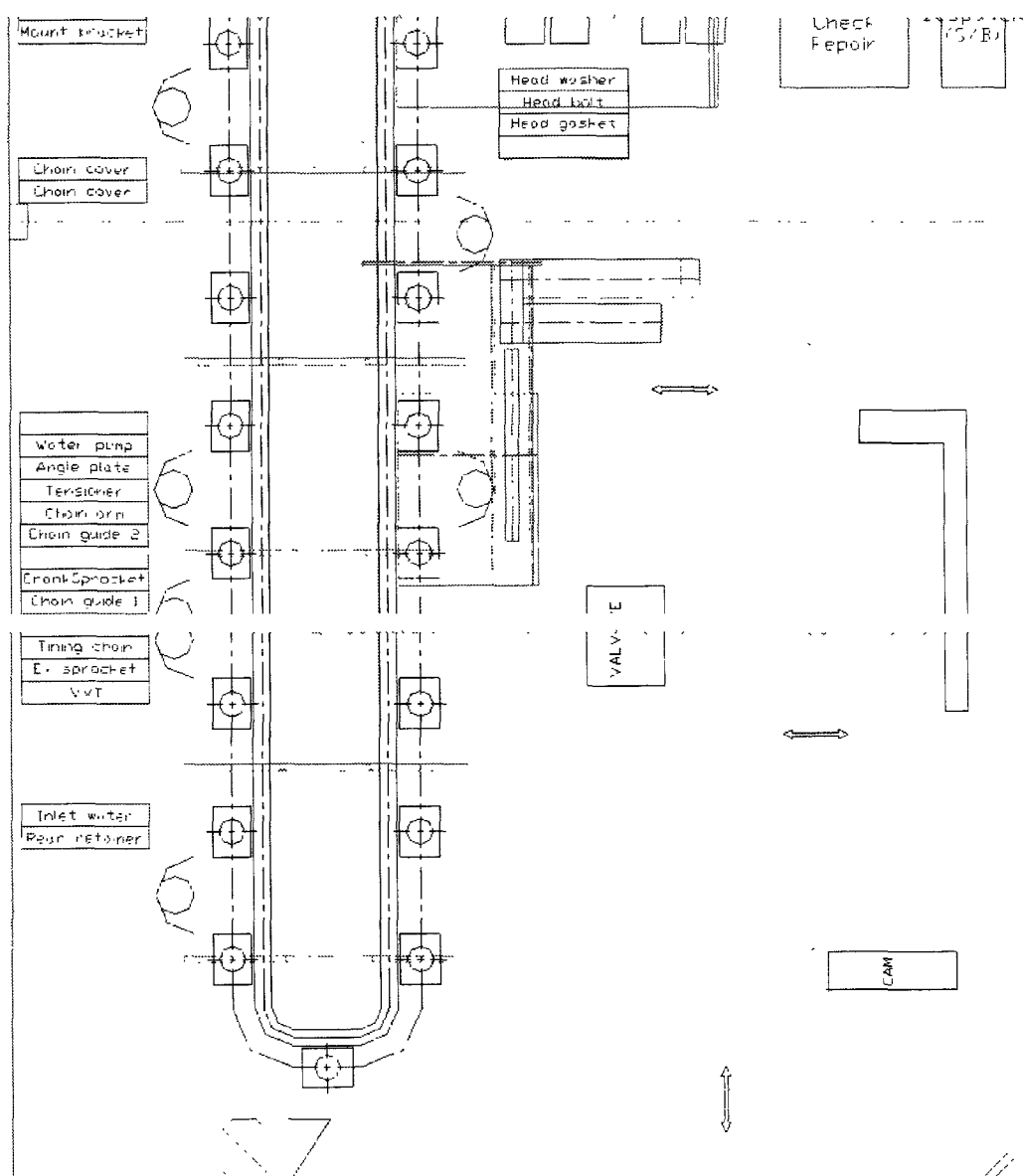
Appendix 1: Toyota Motor Manufacturing France

1.1 Toyota business relationship - 2003

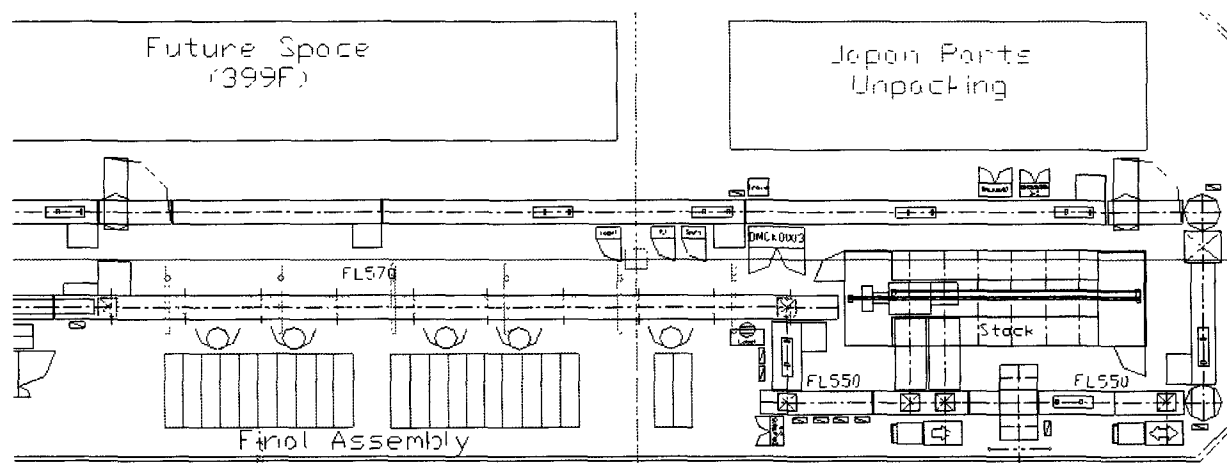


1.2 Engine Assembly Line Layout





From Pre 1 till Main 2 (gazole engine assembly line)



Final gazole engine assembly line

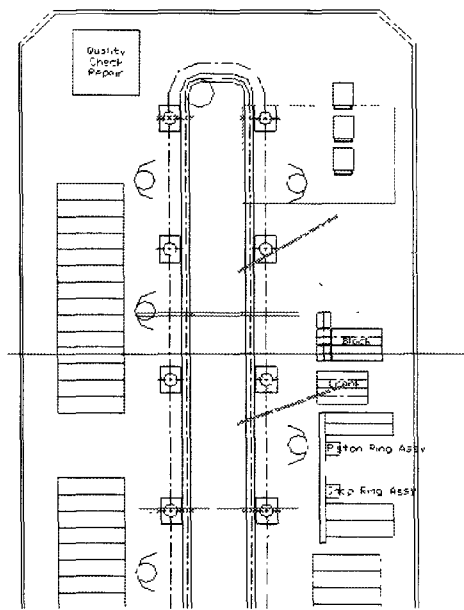


Figure-1: Lay out of diesel engine assembly line

1.3 List of SPC charts for Engine assembly line

The list of all processes of the engine assembly line is described in the table below. These all processes were verified through SPC chart in order to observe the process variation.

TEAM	Process	Spare parts and process	Doc. N°	QCS
PRE 1	1	Oil pressure switch	1/57	K 240
	1	Engraving depth	106	K005
	1	Confirmation of the number to be engraved	106	K005
	1	Engraved status	106	K005
	2	Oil relief valve	2/57	K045
	2	Pins height place	107	K015
	2	Height of the oil pump pin	111	K070
	2	Perpendicularity of the transmission pins	117	K220
	2	Height of the transmission pins	117	K220
PRE 2	4	Quantity of oil on crankshaft	108	K040
	4	Crankshaft cap	3/57	K045
	5	Crankshaft rotation		K047
	6	Con rod cap bolt	109	K060
	6	Con rod cap bolt	4/57	K060
	6	Connecting rod caps assembly	110	K060
	6	Assemblage des connecting rod cap	110	K060
	6	Insertion height of piston axis	124	P 021
	7	Oil pump assembly	5/57	K085
	7	Chain jet squirt assembly	15/57	K080
	7	Jig cleaning of oil pump lubrication		K085

	8	Cylinder head	6/57	K120
	8	Lubrication of the cylinder heads screws	113	K120
	8	Weight of FIPG of cylinder head gasket	103	K090
PRE 3	9	Camshaft position	112	K105
	9	Open crankcase ventilation filter	7/57	K205
	9	Camshaft cap-exhaust	8/57	K125
	9	Admission - Camshaft cap - inlet	9/57	K125
	9	Camshaft cap – stay	10/57	K125
	10	Camshaft position sensor	22/57	K215
	10	Retained plate of rear joint	11/57	K235
	10	FIPG weight of rear retainer	101	K230
	10	Excess joint of rear retainer	118	K225
	10	Excess pin of rear retainer		K220
	10	Support thermostat	201	K455
	10	Thermostat	12/57	K380
	11	Water temperature sensor	21/57	K385
	11	Water pump	32/57	K140
MAIN 1	12	Variable valve timing	13/57	K250
	12	Exhaust camshaft sprocket	14/57	K255
	12	Timing chain N° 1	16/57	K260
	13	Timing chain N° 1	17/57	K260
	13	Chain arm	18/57	K275
	13	Timing chain tensioner	19/57	K285
	14	Chain cover / nut 14	23/57	K295
	14	Chain cover / bolt 12	24/57	K295
	14	Chain cover / bolt 10	25/57	K295

	14	Chain cover / nut 10	26/57	K295
	14	PIPG weight of chain cover gasket	104	K290
	14	Chain cover of 2SZ	105	K 290
	14	Excess joint Chain cover	119	K287
	15	Lug	206	K300
	15	Chain cover support		K460
	15	Front motor bracket assembly nut and bolt	27/57	K300
	15	Bolt of 12	27b/57	K300
	15	Bracket on chain cover	202	K450
	16	Cylinder head cover – bolt	28/57	K325
	16	Cylinder head cover – nut	29/57	K325
	16	Spark plug fitting	30/57	K330
	16	Spark plug specification	120	K330
MAIN 2	17	Turbo direct injection specification		K405
	17	Ignition coil specification	44/57	K405
	17	Oil crankcase ventilator	31/57	K315
	17	Oil strainer nut and bolt	33/57	K340
	17	Crank position sensor	37/57	K305
	18	Oil pan 1SZ green bolt	34/57	K350
	18	Oil pan bolt golden 10	34b/57	K350
	18	Oil pan 1SZ nut	35/57	K350
	18	Oil pan 2SZ nut 10	35b/57	K350
	18	Oil pan 1SZ golden bolt	36/57	K350
	18	Weight FIPG of oil pan gasket	102	K345
	18	Oil pan 2SZ bolt 14	36b/57	K351
	19	Oil drain plug	38/57	K355

	19	Rear en plate assembly	39/57	K360
	19	Flywheel	40/57	K365
	19	Tightening torque screw M10 2SZ of oil pan		K351
	20	Crankshaft pulley	42/57	K395
	20	Gearbox cover	41/57	K375
	20	Engine bracket	45/57	K390
	20	Clutch cover pin	122	K375
	20	Pin size of fly-wheel	125	K370
	21	Water pump pulley	43/57	K310
	21	Delivery pipe assembly	20/57	K211
	21	Jig cleaning of lubrication of delivery pipe assembly	116	K211
PRE 1	23	Water drain plug	46/57	K245
	23	Oil filter union 1sz 2sz	47/57	K151
	23	2 SZ braket oil filter assembly		K151
	23	Oil filter bracket 2sz	47b/57	K151
	23	Oil filter	48/57	K150
	23	Cleaning of Jig of lubrication of oil filter	114	K150
	P1 FINAL	Knock sensor pin		K410
	P1 FINAL	Knock sensor	49/57	K410
	P1 FINAL	Inlet manifold	50/57	K420
	P1 FINAL	Confirmation of engine sticker	115	K155
	P2 FINAL	Throttle body bracket	51/57	K425
	P2 FINAL	Lubrication status of throttle body	126	K425
	P2 FINAL	Throttle body bracket	52/57	K425
	P2 FINAL	Throttle body bolt 10	53/57	K425

FINAL	P2 FINAL	Bracket chain cover	203	K425
	P3 FINAL	Exhaust manifold	54/57	K440
	P3 FINAL	Bracket support of throttle body	207	K 475
	P3 FINAL	Bracket cylinder block	208	K 485
	P3 FINAL	Anti suppressor	209	K 490
	P3 FINAL	Support exhaust manifold bolt	55/57	K445
	P3 FINAL	Support exhaust manifold nut	56/57	K445
	P3 FINAL	Bracket support oil filter	47t/57	K 151
	P4 FINAL	Bracket	205	K 455
	P4 FINAL	Bracket optional	204	K 460
	P5 FINAL	Engine earth	57/57	CVIS-1010-R5
	P5 FINAL	Thermal protection	127	K 447
	P5 FINAL	Verification of engine earth		K506
	P5 FINAL	Specification control		K600

Table-1: List of SPC charts for Engine assembly line

1.4 Skill matrix chart for EAS teams

Skill Matrix of TMs

Team: Yellow

Dated: W245

TMs	Pre 1		Pre 2						Pre 3			Main 1					Main 2					Pre 1		Final					Repair
	P01	P02	P04	P05	P06	P07	P08	P09	P10	P11	P12	P13	P14	P15	P16	P17	P18	P19	P20	P21	P22	P23	P1 F	P2 F	P3 F	P4 F	P5 F	Repair	
TM1																													
TM2																													
TM3																													
TM4																													
TM5																													
TM6																													
TM7																													
TM8																													
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TM36																													
TM37																													

Good process skill
Intermediate process skill
Basic process skill
Good process skill & can train other TMs

Figure-2: Skill matrix chart for the "Yellow" team

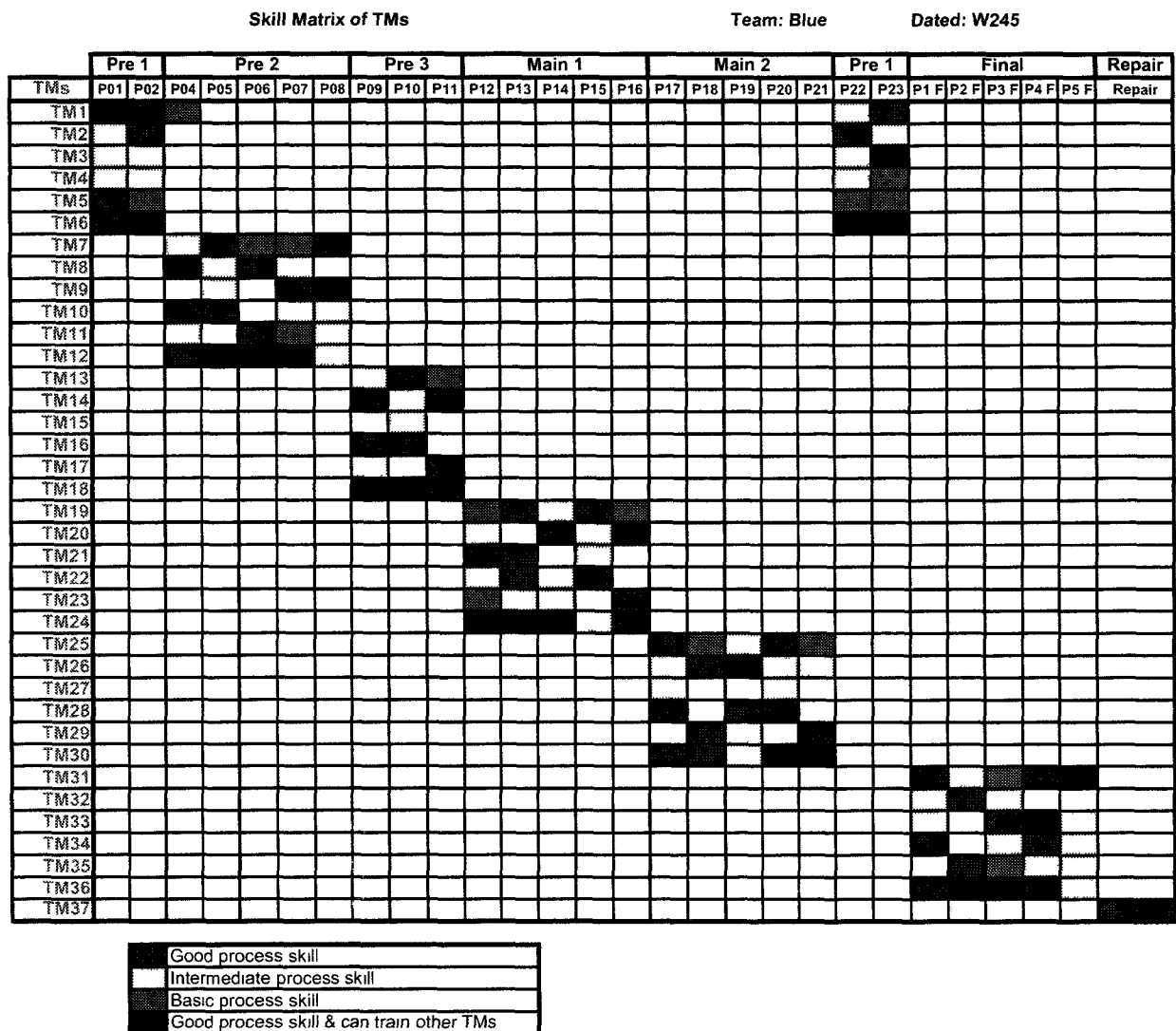


Figure-3: Skill matrix chart for the “Blue” team

1.5 Some database windows of repair activities

The major windows of the data base are shown below:

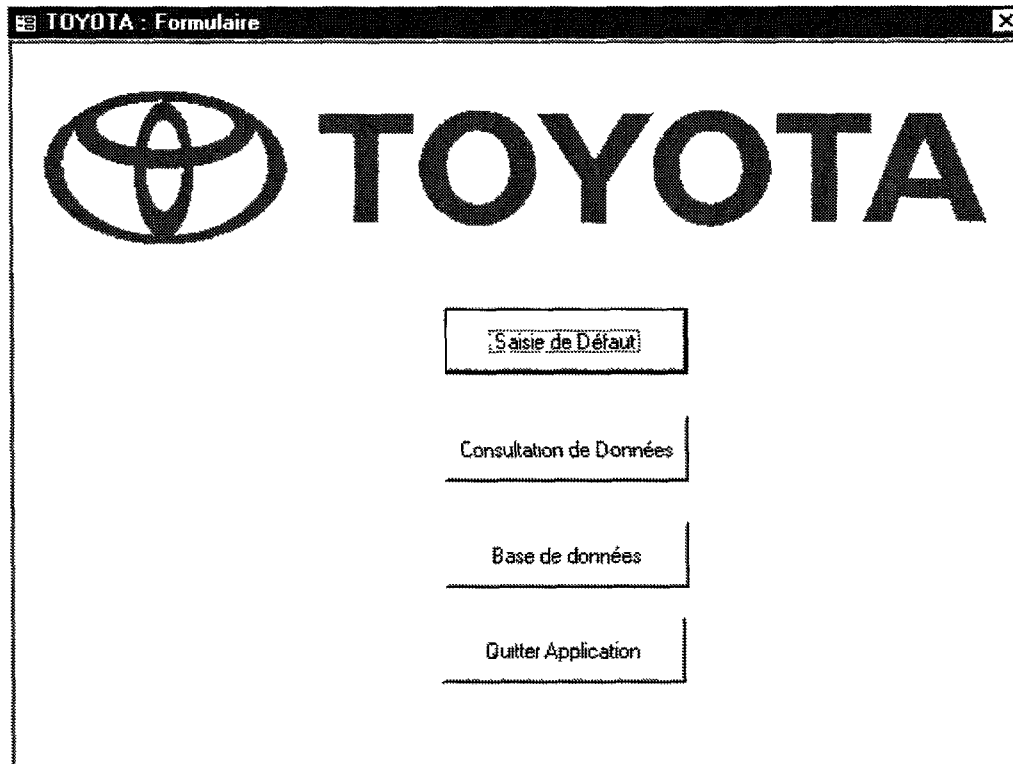


Figure-4: The major window consists of four options including data entry, survey, data base access and to quit the application

The image shows a software window titled "REPAIR MOTEUR". It contains a form with several fields. The first field is "Date" with the value "18/04/2003". The second field is "N° Moteur" with the value "123785". The third field is "Responsabilité" with a dropdown menu showing "LOG". The fourth field is "Team" with a dropdown menu showing "BLEU". The fifth field is "Nom du Recuperateur" with the value "CD". The sixth field is "Defaut" with the value "FAISCEAU NON MONTE". The seventh field is "Reparation Effectuée" with the value "OK". At the bottom of the window, there is a toolbar with several icons: a left arrow, a right arrow, a double left arrow, a double right arrow, a magnifying glass, and a power button. The window has a standard Windows-style title bar with a close button (X) on the right.

Figure-5: When we click the button "Enter Data" the following window appears. This window consists of several items including date, engine number, responsible zone, team, person responsible for repair, defect and nature of repair done

Consultation : Formulaire

Nombre de défaut/5

Defaut par Semaine

TEAM DEFAULT

TEAM DEFAULT
DETAIL

TEAM DEFAULT
EQUIPE

DETAIL TEAM
DEFAULT EQUIPE

GRAPHS TEAM

+

Figure-6: The above window appears when we click the button "Data Survey" from the major window. It includes several possibilities to defects, defects per week, with details, according to team, with graphical representation

Semaine Numero: 17		
Date	mercredi 23 avril 2003	
NOMBRE DE DEFAUT	BLEU	9
NOMBRE DE DEFAUT	JAUNE	7
TOTAL NOMBRE DE DEFAUT CE JOUR		16
Date	mardi 22 avril 2003	
NOMBRE DE DEFAUT	BLEU	16
NOMBRE DE DEFAUT	JAUNE	5
TOTAL NOMBRE DE DEFAUT CE JOUR		21
TOTAL NOMBRE DE DEFAUT DANS CETTE SEMAINE		37

Figure-7: Defects for the month of March 2003 extracted from the database

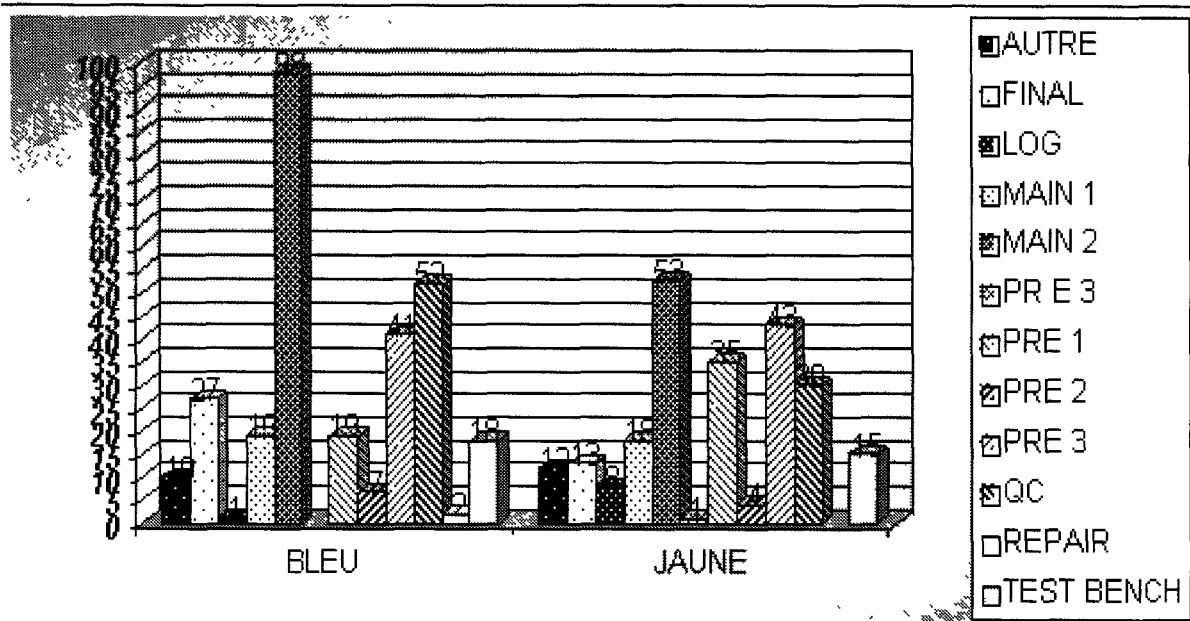


Figure-8: Graphical representation of defects teams wise

Répondabilité	Nombre de défaut
Semaine Numéro 17	
TEST BENC	3
QC	7
PRE 3	7
PRE 1	5
MAIN 2	4
MAIN 1	5
LOG	1
FINAL	4
AUTRE	1
TOTAL DEFAULT	37
Semaine Numéro 16	
TEST BENC	4
REPAIR	1
QC	29
PRE 3	14
PRE 2	3
PRE 1	5
MAIN 2	13
MAIN 1	13
LOG	2
JUNDATE	1
FINAL	28
AUTRE	9
TOTAL DEFAULT	122

6

Figure-9: Number of defects with responsible zone of week 17

Date	mercredi 23 avril 2003	
Equipe BLEU	N° Moteur	
	125578	CACHE CULASSE CASSE
	125608	CULASSE GRIFFE
	124820	FASCEAU CASSE
	125459	FUITE JOINT FILTRE A HUILE
	125736	INJECTEUR PINCE
	125516	JOINT HEAD COVER PINCE
	125445	LEGER BRUIT BAS MOTEUR
	125703	STUD ECHAPPEMENT FOIRE
	125616	VIS VOLANT MOTEUR FOIRE
NOMBRE DE DEFAUT		9
Equipe JAUNE	N° Moteur	
	125290	CULASSE GRIFFE
	125201	HEAD COVER CASSE
	125343	HEAD COVER CASSE
	124417	HEAD COVER CASSE
	124888	JOINT DE CULASSE
	125352	JOINT DE FILTRE A HUILE PINCE
	125043	MANQUE PIECE
NOMBRE DE DEFAUT		7
TOTAL NOMBRE DE DEFAUT CE JOUR		16
TOTAL NOMBRE DE DEFAUT DANS CETTE SEMAINE		37

Figure-10: Details of defects for the week 37

Appendix 2: Sanofi Pasteur

2.1 Preliminary definition of terms used in pharmaceutical industry

Many terms used in pharmaceutical industry have different meanings. The terms, as used in this chapter, are defined below. The definitions for some terms will be expanded in later sections. Preliminary definitions are given as follows:

Business Continuity: Business Continuity is the approach to managing risks to ensure, at all times, an organization can continue to operate to, at least, a pre-defined minimum service level.

Change Management: The process for tracking changes to IS systems and environments.

GxP: GxP is any acronym that groups together the following compliance practices:

cGMP – Current Good Manufacturing Practices

GLP – Good Laboratory Practices

GCP – Good Clinical Practices

Qualified: Documented evidence that the item under consideration is installed and operated according to pre-determined specifications.

Acceptance Testing: Functional acceptance tests of the system performed with the supplier/developer.

Incident: An incident is the final expression of a particular problem stated by a user, or identified by administrators. Incidents are generally system faults, errors or problems reported by the user. An incident may concern:

The production applications

The database structure

The components of the infrastructure (platform, network, operating system)

The workstations

Service Level Agreement: Document that describes the quality service level required for a given project.

21 CFR Part 11: FDA code of US Federal Regulations, Title 21, Part 11 (21 CFR Part 11) Electronic Records; Electronic Signatures that defines parameters by which pharmaceutical companies can author, approve, store, and distribute records electronically.

AFSSAPS: Stands for French Health Products Safety Agency is the French authority for all safety decisions taken concerning health products from their manufacturing to their marketing, *i.e.*: medicinal products, raw materials for

pharmaceutical use, organs, tissues and cells and products of human and animal origins, etc.

BPF: Stands for “Bonnes Pratiques de Fabrication”. It is the equivalent of GMP.

cGMP: Stands for current Good Manufacturing Practice is an international set of quality regulations and guidelines applicable to the manufacture, testing and distribution of drugs, medical devices, diagnostic products, biological for human or veterinary use, etc... FDA ensures quality product applicable to GMP via 21 CFR Part 210 and 211 regulations.

CMM: The Capability Maturity Model (CMM) is a method for evaluating and measuring the maturity of the software development process of organizations on a scale of 1 to 5. The Software Engineering Institute (SEI) at Carnegie Mellon University in Pittsburgh, USA, developed the CMM.

Change Management: The complete set of processes employed for tracking all changes from existing and new systems, applications, and environments defined by a respective pharmaceutical regulatory conformance and to manage systematically the effects of change.

Computerized System: A system that includes software, hardware, application software, operating system software, supporting documentation, ... e.g. automated laboratory systems, control systems, manufacturing, clinical, or compliance monitoring database systems, etc.

DRP: Stands for disaster recovery plan is the plan for business continuity in the event of a disaster that destroys business resources. The goal of DRP is to recover the technical infrastructure that supports business continuity, in the event of a serious incident in the least possible time.

FDA: Stands for Food & Drug Administration, the branch of US federal government which approves new drugs for sale and is responsible for the for ensuring the safety and effectiveness of all drugs, biologics, vaccines, and medical devices, including those used in the diagnosis, treatment, regulation, etc. for USA.

GCP: Stands for Good Clinical Practices is an international set of quality regulations and guidelines for design, conduct, monitoring, recording, auditing, analysis, and reporting of studies applicable to the clinical or human studies in the evaluation of drugs, medical devices, biological product, etc... FDA ensures quality product applicable to GCP via 21 CFR Part 50, 54 & 56.

GLP: Stands for Good Laboratory Practices embodies an international set of quality regulations and guidelines applicable to the non-clinical studies in the evaluation of drugs, medical devices, biological product, etc... GLP provides a framework within which FDA ensures laboratory studies are planned, performed, monitored, recorded, reported and archived under 21 CFR Part 58.

GxP: GxP is generalization of any quality guidelines used in the pharmaceutical industry that groups together the following compliance practices, cGMP: Current Good Manufacturing Practices, GLP: Good Laboratory Practices, GCP: Good Clinical Practices.

ISO: Stands for the IS standards established by International Organization for Standardization who is responsible for a wide range of standards for large number of industries. ISO provides a means of verifying that a proposed standard has met certain requirements for due process, consensus, and other criteria by those developing the standard.

Lifecycle Model: A life-cycle model is the order in which a series of processes are performed to create/update a product or service. Examples include a Waterfall, Incremental Build, and Evolutionary Build approach.

SLA: Stands for Service Level Agreement and provides the predefined and standard level of services available in the organization and ease the process to establish a solution-specific SLA.

SOP: Stands for Standard Operating Procedure is a written document that describes in details how a particular procedure or method is executed for repetitive use. It is generally intended to standardize the procedure performance.

Spiral Model: It is also known as the spiral lifecycle model, is a systems development method used in information technology. This model of development

combines the features of the prototyping model and the waterfall model. The spiral model is favored for large, expensive, and complicated projects.

Validation: Documented evidence providing a high degree of assurance that a specific process under consideration does what it purposes to do. Validation deals with the entire system lifecycle to ensure a system satisfies user requirements, meets compliance expectations and adequately maintained to provide a secure environment with accurate, reliable, and traceable information from conception to retirement. The term is also used to describe the overall validation approach including qualification. Validation includes but is not limited to manufacturing processes, equipments, computerized system, etc.

Validation Plan: A plan created by the customer to define validation activities, responsibilities and procedures.

Vendor Audit: A systematic and independent examination to determine whether quality activities and related results comply with a documented Quality System and whether this documented Quality System is implemented effectively and is suitable to achieve the contractual requirements placed by the customer.

V Model: The V-model is a software development model, which describes the activities, and results that have to be produced during software development.

Waterfall Model: Introduced in 1970, the waterfall model is a software development model describing the theoretical approach to software development in which development is seen as flowing steadily through the phases of requirements analysis, design, implementation, testing (validation), integration, and maintenance. It is the basis for the V-model used in the pharmaceutical industry.

2.2 Some extracts of the IS quality manual

I worked on several parts of the IS quality manual in collaboration with ISQV teams in France, USA and Canada. Some extracts of IS manual are presented below including the following sections:

- Customer support including support center and incident management

- Supplier/consultant management
- Regulatory requirements
- Technology acquisition
- System decommissioning
- DRP
- SLA

2.2.1 Customer Support including Support Centre

Customer Support is committed to assure quality services in meeting the customer requirements and working with all the relevant users in the company. The customer support assures the satisfactory guidelines and support by respecting quality, delay and cost, in meeting the standards and best practices of Information Solutions in acceptable time. The customer support enhances the *Sanofi Pasteur* strength by providing all necessary services to meet customer satisfaction and needs at their sites. The customer support ensures the best-fit solutions for the customers.

Customer Demand: The customer support handles all customer demands and verifies the actions taken to enhance user productivity by quickly and efficiently addressing all issues with friendly and responsive service. The customer demand (network user accounts, equipment - workstation, devices or additional components, access to shared IS resources etc..) are managed by the IS Customer Support Centre. The support centre offers user with a single point of contact for all technology needs and requests, and to better manage customer demand based on specific customers' needs and preferences.

Method: Satisfying the user is the vital responsibility of the customer support, which depends on the resources available to them. There are various resources used by customer support in order to allow the company users to use their computer tool and work in the most optimal conditions. These include

support centre, advanced technical support, external support, DISC “demandes informatiques service client” or (Client Service Information Requests), asset management, service desk and customer complaints.

Support Centre: The support centre (Help Desk) belongs to IS customer service team, which is a critical resource enabling support professionals to resolve the incidents promptly and accurately in least possible/acceptable time. The role of the Help Desk is to offer quality telephone, e-mail and voice mail assistance in order to allow the company users to use their computer tools and work in the most optimal conditions.

Primary functions of Help Desk: It include

- To record the call and orientation according to the type of desired troubleshooting
- To analyze and diagnose all the incidents
- To solve, register and assure all incidents handling from opening till closure when possible with the help of concerned teams
- To provide the best answer to the user on the systems supported by Information Solutions
- To assign the day-to-day related incident to technical support team
- To inform relevant team when end user are not satisfied with the incidents resolution
- To diffuse any particular information provided by technical support team for the concerned end user

Help Desk ensures that all service level agreements are being met when assigning the incident to the relevant team according to the incident level support. The agreed maximum time to bring a solution to an incident is function of the level of priority set by the service as well as gravity of the incident or in case of escalation.

Advanced Technical Support / Project Team (In France): The advanced technical support / project team is responsible for completion of the incidents diagnosis after analysis. The team assigns the incident to the relevant technical support team according to the case.

The External Support (In France): The external support completes the incident diagnosis after analysis. It solves, documents and closes the incidents, along with the advanced technical support.

DISC (In France only): The DISC “demandes informatiques Service Client” manages the online client request send by the user. The system makes it possible to reply the answer/solution asked by the clients in earliest possible time. The clients can verify their demand on line at any time and they are informed by email after a proper action taken on the request.

Asset Management: Asset management assures the control of equipment and associated supported cost in terms of delay, quality and cost while maintaining the IS requirements and standards. This may include hardware, software or computer peripheral. Ex: Laptop, desktop, printer, fax machine, scanner, software, etc. It assures the coherent working environment (hardware, software) standards and update of all equipments for their official use.

Service Desk: Service desk handles the requests related to user accounts, mailboxes and SecurIDs (creation, modification, transfer, deactivation and expiration). Service Desk and site installation teams are responsible for the following tasks:

- Installs and maintains the hardware and software components that are necessary to the execution of desktop operations.
- Identifies and analyzes installation problems
- Engage not to change any procedure without administrator reference in order to insuring Desktop compliance.

Customer Complaints: The customer complaints are registered online when the user is not satisfied with the solution / resolution proposed by the

customer support. These complaints and suggestions are sent to the IS senior management in order to analyze again the customer need before taking a final decision on the customer inquiries.

Site Specifics: A common customer support procedure has been established for all French sites. The service DISC is available at the France site only. The Help Desk in France is to be used as a primary Help Desk for France and International sites. The North America Help Desks are to be used as a primary Help Desk for North American sites. The service desk responsibilities are handled by IS Security in the NA.

2.2.2 Incident Management

The IS Department reports, tracks, and resolves all system and application incidents that occur. Incidents can be reported by the business user or the IS technical team (Infrastructure, Network, Operations, etc.). A few examples of incidents reported by business users are: servers are not responding and loss of network connectivity. A few examples of incidents reported by the IS technical teams are: power outages and backup failures.

Method: For user reported incidents – The Support Centre receives a phone call or e-mail from the business user describing the incident. The Support Centre then enters the incident into the tracking tool and analyzes it, if possible, solved by the Support Centre. If the incident is not immediately resolved, the incident is escalated to the IS Technical Team. User is informed with information or a solution is documented within the tracking tool.

For IS Technical Team or Business Analyst reported incidents – The IS Technical Team enters the incident into the tracking tool and analyzes is, if possible, solved by the Support Centre. If the incident is not immediately resolved, the incident is escalated to External Support. If necessary, a communication to the user community is delivered.

2.2.3 Supplier / Consultant Management

The supplier / consultant management deals with the set of rules in order to select a new supplier / consultant which depends on the roles and responsibilities of the supplier / consultant at *Sanofi Pasteur*.

Method: The supplier / consultant management process defines the supplier profile, which includes the essential know-how and knowledge required in order to complete the mission. The knowledge could be technical, but also methodological, organizational or related pharmaceutical expertise.

The supplier capability analysis is done through the resume provided by the supplier.

The identified applicants are then preceded for an interview. The objective of the interview is to verify the required key elements (motivation, technical, functional and relative pharmaceutical experience, team work, etc...)

After selection, the integration process of the new supplier is launched to determine the knowledge and competency transfer according to the supplier / consultant level and nature of the mission. Training is given to supplier to provide him the basic knowledge of the company's organization and operation. The competency transfer from supplier is also documented to realize the capacity of the supplier. Records are properly documented and maintained according to the regulations.

Site Specifics: A common supplier / consultant management procedure is established at each *Sanofi Pasteur* site according to their needs. The purchasing group is also involved assists by developing the contractual agreements and negotiating prices for supplier / consultant management.

2.2.4 Regulatory Requirements

Sanofi Pasteur is required to meet a variety of regulatory requirements. These requirements address issues including public health and privacy,

manufacturing, clinical trials, and financial disclosures. Individual countries/regions may have similar but separate regulations that could impact *Sanofi Pasteur*. In addition, these requirements are periodically updated or clarified by the regulatory bodies through guidance and policy documents. These regulations may only apply to specific applications (or “modules” within an application) based on their usage. In addition, the various agencies may issue guidance documents to supplement their formal requirements. The applicable regulations are to be included when developing the system requirements.

The following is a partial list of the agencies and regulations impacting IS at *Sanofi Pasteur*.

US Food and Drug Administration (FDA)

- cGMP: Current Good Manufacturing Practices (21 CFR Part 210 and 211) - Regulations applicable to the manufacture, testing, and distribution of a new drug, medical device, or biologic for human or veterinary use.
- GLPs: Good Laboratory Practices (21 CFR Part 58) - Regulations applicable to non-clinical studies in the evaluation of a new drug, medical device, or biologic product.
- GCPs Good Clinical Practices (21 CFR Parts 50, 54, & 56) - Regulations applicable to clinical or human studies in the evaluation of a new drug, medical device, or biologic product.
- Electronic Records; Electronic Signatures (21 CFR Part 11) – Regulations applicable to the creation, modification, maintenance, archival, retrieval, and transmission of FDA regulated electronic records and the usage of electronic signatures.

Note: It is common to refer to the cGMPs, GLPs, and GCPs as the GxPs.

Agence Francaise de Securite Sanitaire dec Produits de Sante (AFSSAPS
- French Agency of Health Safety of Health Products)

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.
- Annex 11 - Computerised Systems
- Annex 12 - Qualification and validation

Health Canada

- GMPs – 2002 Edition Version 2

U.S. Securities and Exchange Commission (SEC)

- Sarbanes-Oxley Act Section 404 – U.S. Federal regulation of public company corporate governance and reporting obligations

U.S. Department of Health and Human Services

- Health Insurance Portability and Accountability Act (HIPAA) - Governs the provision of health benefits, the delivery and payment of healthcare services, and the security and confidentiality of individually identifiable, protected health information.

2.2.5 Technology Acquisition

Technology acquisition process describes best practices for use in the acquisition of products. The acquisition of IS technology (software and hardware) must be monitored to prevent the uncontrolled implementation of systems. This control is required for security, regulatory compliance, technology acceptance, supplier evaluation, cost control, etc.

The IS department is committed to working with *Sanofi Pasteur* users to evaluate, select, implement and maintain IS systems. *Sanofi Pasteur* purchasing group works closely with IS to ensure that all prerequisites are met before a system is purchased. ISQV should be consulted for advice and assistance concerning whether the desired supplier has been audited.

Method: When considering acquisition of a software or hardware technology, an understanding as a rational tool to support IS solution selection process is required. The technology should confirm the requirements in the company's context. A successful acquisitions process is based on careful planning, which usually starts with a "requirements analysis". The purpose of this analysis is to define currently existing manual and/or automated procedures and to identify future needs.

The following outlines the important factors associated with technology acquisition.

Requirements: While investigating potential solutions and benchmark, following points should be considered.

- List of the required functionalities
- Compatibility with IS Strategy (technical infrastructure must fit within *Sanofi Pasteur* standards)
- Solution lifecycle (long term investment, etc...)
- Approval and recommendations of the appropriate steering committee if any

Evaluation Criteria: Solution and supplier evaluation is generally based on selection method defined by project including:

- Functional coverage: Solution ability to handle *Sanofi Pasteur* critical business processes and to answer the business needs, flexible according to changing factors, user friendliness and simplicity.
- Risk management: It includes risk (technical, commercial, pharmaceutical, etc...) analysis, supplier audit, technology supplier reputation with investment capabilities, well-known technology with live references/robustness of the solution, supplier support / maintenance.
- Implementation time: Easiness of the solution implementation.

- Cost: Solution cost, return on investment.
- Technical coverage: Integration in *Sanofi Pasteur* current architecture, capability to support the future evolution.

The appropriate steering committee approval is required before preparation of a request for proposal with purchase department.

Assessment: Assessment of technology acquisition makes use of the questionnaire defined in the evaluation phase. It involves supplier audit, evaluation assessment with project team, team recommendations, a site visit for the recommended solution, to complete final evaluation form, etc.

Decision: Decision process involves the team recommendation, evaluation results, and presentation to IS management team (local or global depending on project scope). Upon approval of ISMT present it to the project steering committee to deliver final decision on the selected solution.

2.2.6 System Decommissioning

System decommissioning can be a complex undertaking that must be thoroughly planned and documented. It includes the following:

- To assure that the withdrawal considers the latest regulations.
- To verify that the information is preserved as per record retention policies.
- To guarantee the respect of processes control of the pharmaceutical impacts.
- To define internal rules for the archiving elements of the application.

Considerations: Following are the important considerations to ensure the smooth system decommissioning.

- Adequate communication to ensure awareness of the system decommissioning: It involves the application owner, system owner. When

an application owner identifies a system decommissioning with action plan with system owner, an agreement from QA is obtained to define all necessary details. The CM process is used to track all changes related to the system decommissioning within IS and also to avoid any impact on other systems. QA involvement is needed for regulated applications.

- Process preventive actions in order to maintain the conformity of these processes and of data in order to assure the respect of the 21CFR part 11 for FDA regulated applications.
- Record Retention: It should be maintained in order to access information including data, audit trail, etc in case of need.
- Storage of the electronic documents of the applications: It includes archiving the source program, documentation, and the relevant data.
- Update to Disaster Recovery Plan: It should be done in order to recover the system if case arises. DRP details are mentioned in the section 3.1.7.
- Deactivating of SOP: If system decommissioning requires deactivation of any SOP, it will be done after appropriate verification.

Method: The withdrawal of an application is an element of the application life cycle. It is thus managed under change management / change control because of strong impact of the modification. It involves detailed decommissioning strategy including planning, necessary consideration, conformity, DRP, archiving, system inventory, etc.... to ensure the smooth withdrawal while maintaining the system. The general process is depicted in *Figure-11*.

Archiving: Archiving material can be the electronic or paper archive. It handles data (completely taken or partially taken and transferred in the database), programs (part of software package or specific element) and the documents (specification files, general design files, testing files, installation documents, technical documents, etc....).

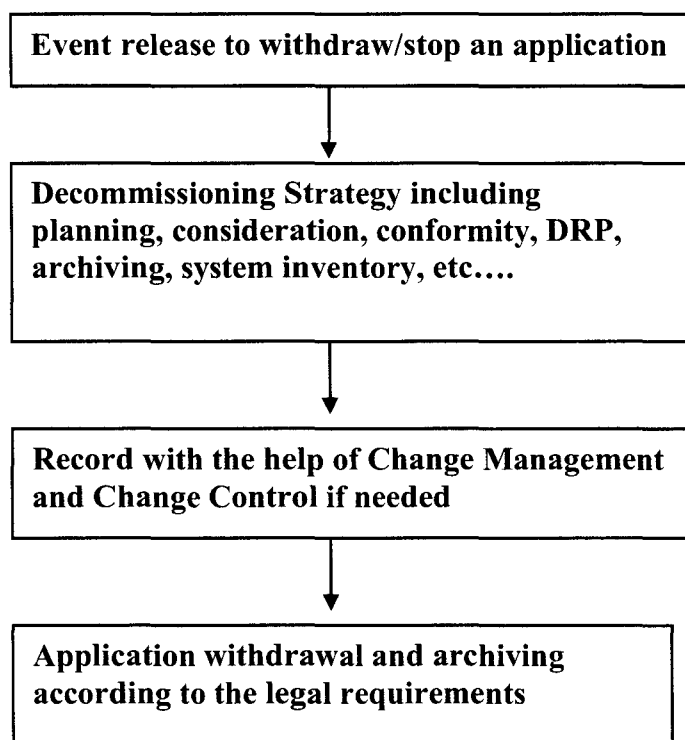


Figure-11: System decommissioning general process

2.2.7 Disaster Recovery Plan (DRP)

A disaster recovery plan is a plan to be followed in the event of a disaster that destroys part or all of a business's resources, including I.S. equipment, data records and the physical space of an organization. The goal of a DRP is to resume normal computing capabilities in as little time as possible. Business Continuity differs from DRP. Business Continuity is the assurance that business processes, systems and infrastructure facilities services have procedures in place to allow the business to continue its operation in case of failure to non-IS related resources. Business Continuity is the approach to managing risks to ensure that all times, an organization can continue to operate to, at least, a pre-defined minimum service level. The business is responsible for managing Business Continuity.

DRP is the approach to recovering the technical infrastructure that supports business continuity, in the event of a serious incident. An effective recovery plan is a live recovery plan. Preparing a DRP enables *Sanofi Pasteur* business to continue to operate in case of a serious disaster.

Objectives: DRP objectives include:

- Organizations are becoming more dependent on the service and record keeping of the IS department. The overall objectives of the Disaster Recovery Plan are to protect corporate resources and employees, to safeguard the organization's vital records of which the data centre has become the custodian, and to guarantee the continued availability of essential IS services.
- The role of this Plan in these objectives is to document the pre-agreed decisions and to design and implement a sufficient set of procedures for responding to a disaster that involves the data centre and its services.
- A disaster is defined as the occurrence of any event that causes a significant disruption in IS capabilities.
- The central theme of the Plan is to minimize the effect a disaster will have upon on-going operations.
- This Plan responds to the most severe disaster, the kind that requires moving off site to a backup facility.
- Occurrences of a less severe nature are controlled at the appropriate management level as a part of the total Plan.

Method: Following are the major stages of a typical DRP:

- Understanding the *Sanofi Pasteur's* activities and how all of its resources are interconnected
- Assessing the *Sanofi Pasteur's* vulnerability in all areas, including operating procedures, physical space and equipment, data integrity and contingency planning
- Risk analysis in case of a major disaster. This is to make a risk matrix for all levels of *Sanofi Pasteur* would be affected in the event of a disaster
- Backup strategy for alternative solutions of data centers facilities, server infrastructure, network, data at outsourced sites, etc....

- Recovery strategy including approach, developing a short-term recovery plan and a long-term recovery plan, including how to return to normal business operations and prioritizing the order of functions that are resumed
- Testing and consistently maintaining and updating the plan as the business changes.

2.2.8 Service Level Agreement

The general Service Level Agreement (SLA) provides the predefined and standard level of services available at *Sanofi Pasteur* for IS solutions, and ease the process to establish a solution-specific SLA. Without specification, the general SLA is applicable to all IS Solutions.

Method: The solution specific SLA is established between the user's department (the solution owner) and the IS department. The role of user department is to define the conditions of use through SOP, quality of the data managed, functional administration, respect of security, and training to meet compliance requirements. Whereas the IS department develops processes and tools to guarantee the adequate availability and performance, technical support and maintenance, and security.

There are four classes of services (gold, silver, bronze and basic) depending on the IS Solution Business criticality impact which are highly business critical, business critical, other production and non-production IS Solutions.

The general SLA SOP defines IS Solutions application applicability, planned stops, supported hours, their availability, level of support for IS monitoring and data recovery.

The IS Solutions are actively monitored in order to solve most of the incident before they impact the use of the solutions.

The SLA takes into account the required recommendation of the IS global security policy, which defines a set of rules and procedures designed to minimize

the threat, attack, compromise, loss of information and vulnerability to unauthorized people.

In case of a disaster, a DRP will be activated by the IS department.

Any change either functional or technical will be handled according to the IS Change Management which provides means of tracking changes to new and existing systems, applications, and environments within the IS department.

The SLA must be regularly reviewed. Any significant changes in the provided services or the organization of the service must be documented in order to guarantee the users with the expected services and it will allow IS to setup the necessary measures to guarantee these services.

For confidential information and legal compliance, the user is responsible to determine the level of confidentiality for all data managed and to inform the IS in case of specific rules to be applied for these solutions.

2.3 Facts and Figures about IS file management tools

2.3.1 Public Folder

In *Sanofi Pasteur*, public folders were created with Microsoft outlook. One can use public folders to share files or post information on an electronic bulletin board. Public folders can also be used to store items such as calendars and contacts that are shared by two or more people. Stored on exchange computers, public folders are created and designed by administrators and other people in the organization who have the appropriate access permissions. These access permissions determine who can view, create, and modify items in the folders. Anyone who uses the e-mail server can read and post to his server's public folders, and can read and post to public folders on other servers.

2.3.1.1 Facts and Figures about shared folder in IS

Main points after verifying the public folders are presented as followings:

Public Folder France: There are 12 public folders in IS France.

12 Folders (level 1) represent: 10.5 Go;

Folder name “Project&Application” size is 6.86 Go uses 65.2% space of total folders;

Service Client (2.55 Go - 90% as Archive Help Desk): 24.2 % of used space;

Others (1.1 Go): 10.6 % of used space;

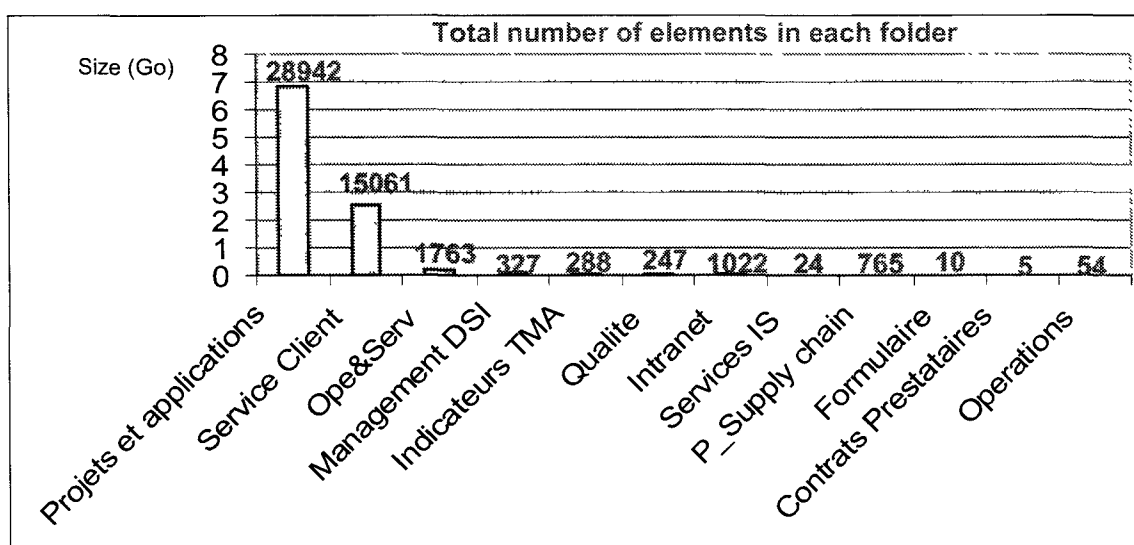


Figure-12: File with size and number of elements (including sub folders) in FR

Public Folder USA: There are 17 public folders in IS USA.

17 Folders (level 1) represent: 60.42 Mb (last date modified on 09/27/2004 for 14 folders / 17);

Deployment Services (31.1 Mb): 51.5% of used space;

Support Services (11.5 Mb): 19.6 % of used space;

15 Others (17.8 Mb): 29.5 % of used space;

Owners: From 1 to 6 owners per folder.

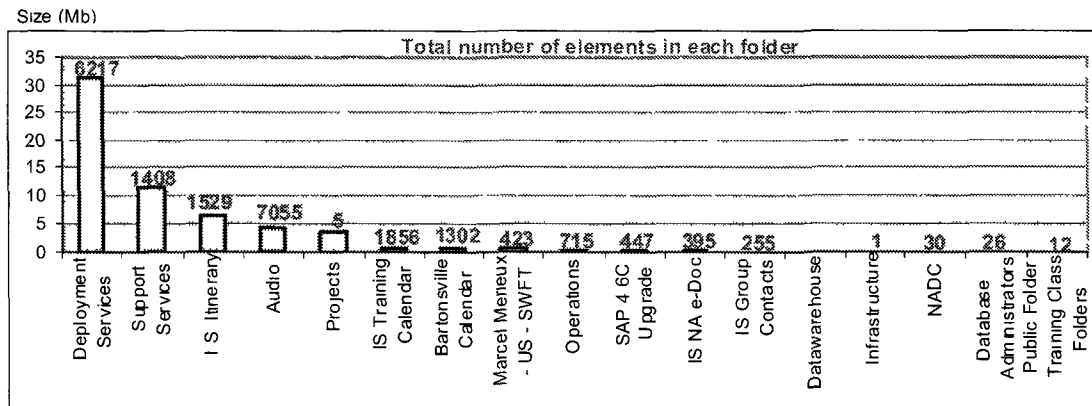


Figure-13: File with size and number of elements (including sub folders) in USA

Public Folder Canada: There are 24 public folders for IS Canada.

24 Folders (level 1) represent: 490.2 Mb (all have a modified date 10/03/2005);

Network Systems (319 Mb): 65.9% of used space;

WISDOM (34 Mb): 7 % of used space;

22 Others (137 Mb): 27.9 % of used space;

Owners: From 2 to 8 owners per folder.

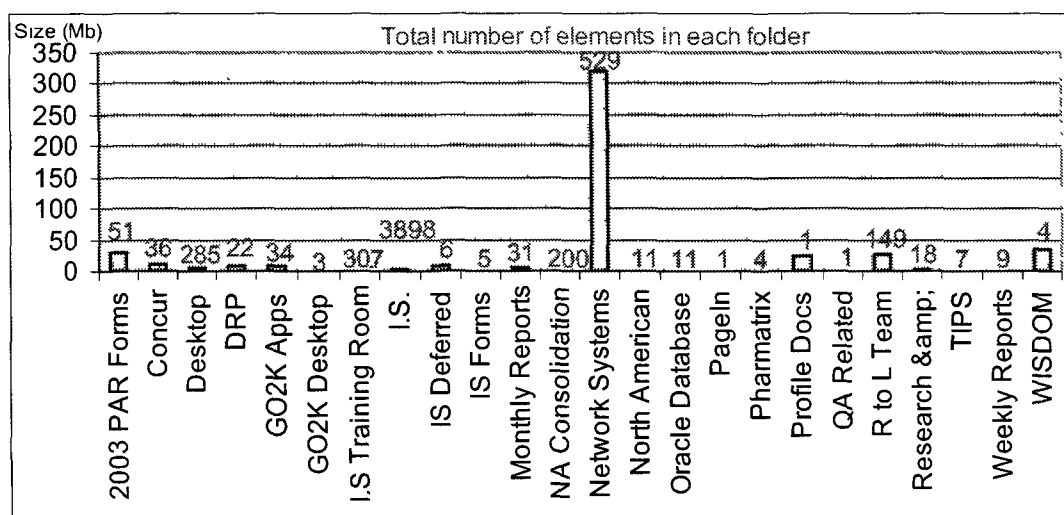


Figure-14: File with size and number of elements (including sub folders) in Canada

2.3.2 eRoom

eRoom enables teams working in different departments, locations, and companies to work as if they were in the same location by providing a single, secure environment to coordinate projects. It is meant for online collaboration and provides an instant visibility into the status of critical projects, program or business plans. eRoom provides a rapidly deployed and easily adopted Web-based collaborative workspace that enables distributed teams to work together in a shared environment efficiently. Project teams around the world can accelerate and improve the development and delivery of products and services, optimize collaborative business processes, improve innovation, and streamline decision-making. eRoom provides distributed business teams the tools they need to share information, capture and preserve knowledge, discuss ideas, resolve issues, and ensure that projects are completed on time, with maximum efficiency and minimal effort.

2.3.2.1 Facts and Figures about eRoom in IS

Total number of *Sanofi Pasteur* eRooms = 959, within 131 (13%) for *IS* departments which represent about 16 Go of space used.

eRoom	Quantity
Global	959
France	400
NA	559
eRoom IS NA	62
eRoom IS Fr	69

Table-2: Total eRooms of Sanofi Pasteur with IS eRoom

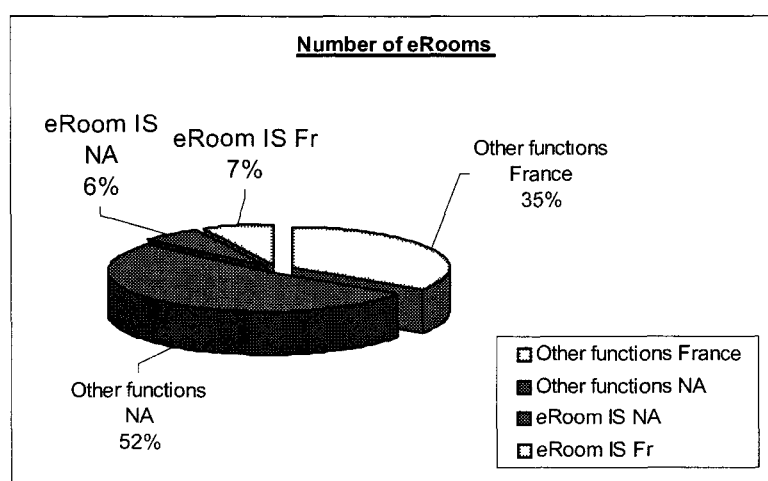


Figure-15: Total number of E-rooms in Sanofi Pasteur

In this study, the *IS* eRooms were considered only.

- eRoom IS France: 69 e-Rooms with 8,5 Go used containing 11,510 documents;
- eRoom IS NA: 58 e-Rooms with 7,4 Go used containing 16,920 documents.

Information Location in E-Rooms

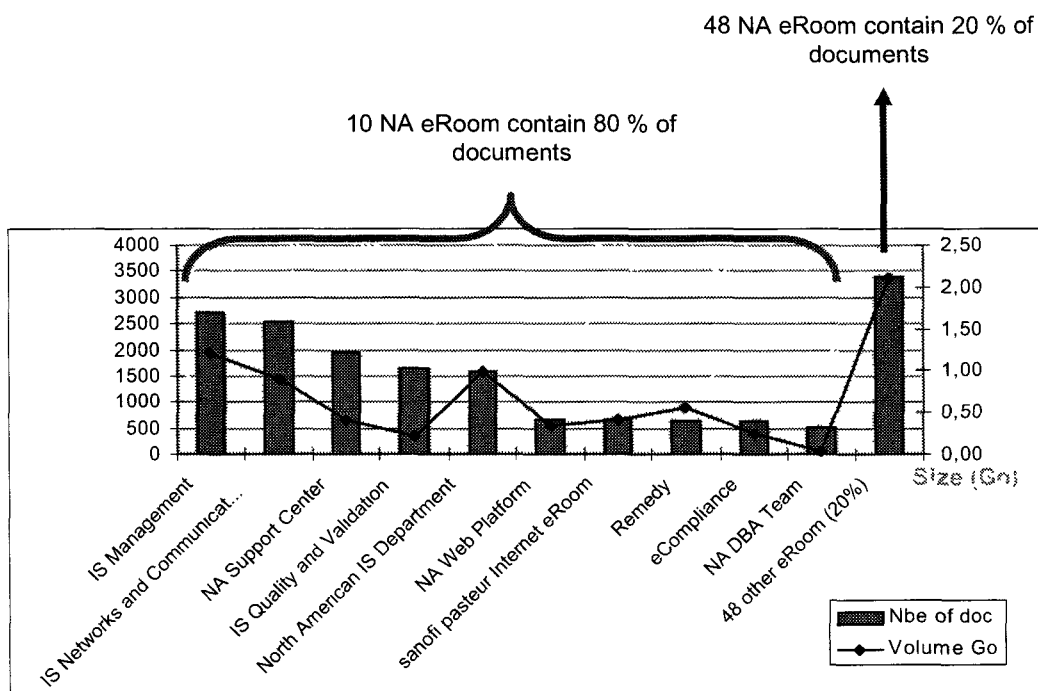


Figure-16: NA e-Rooms containing documents volume in Go

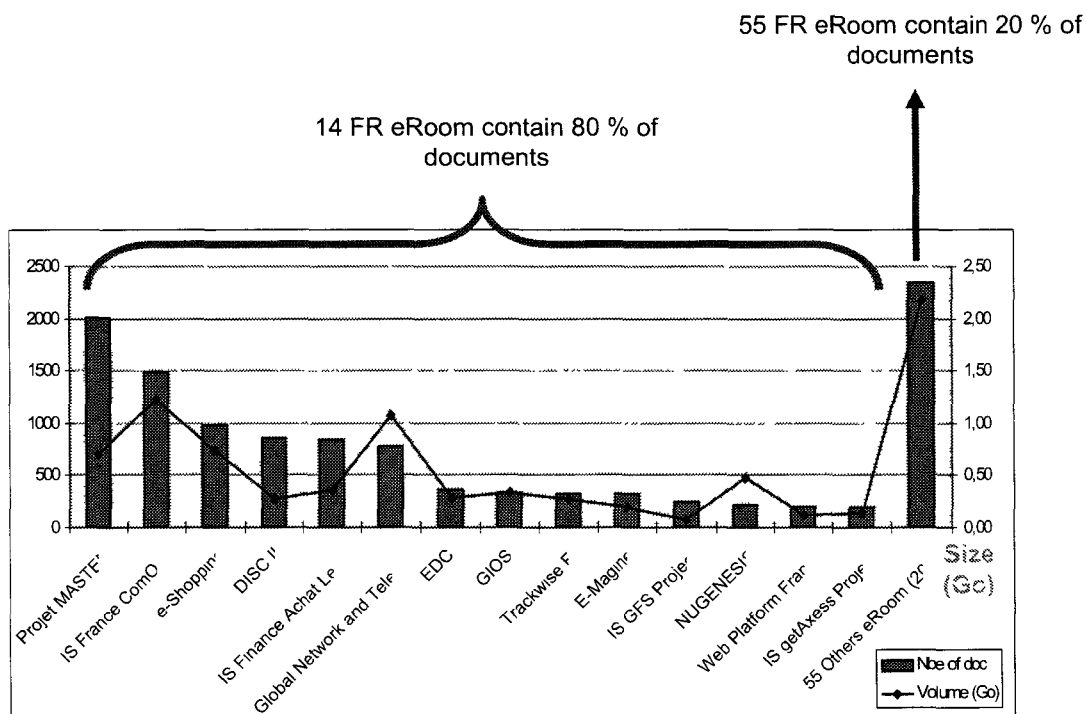


Figure-17: FR e-Rooms containing documents volume in Go

Number of document: 80 % of the documents represent 70% of used space, placed on around 20% of the eRooms.

Used space prospective: 80 % of used space represents 80% of the documents placed on around 20% of the eRooms.

2.3.3 Shared folder

Like a public folder, a shared folder is created to share information with others. The owner of a shared folder can set privileges so that only a select group of users have access to the folder, or the folder can be made available to everyone on the network. In *Sanofi Pasteur*, shared folders were named as J and H drive for France and North America respectively.

2.3.3.1 Facts and Figures about shared folder in IS

IS France: About 2 million (1.985.920) IS files are on Shared Folders (J:/ Drive)

Representing about 480 Go of space used on 700 Go (70% used of the total capacity)

IS NA: About 140.000 (139.904) IS files are on Shared Folders (H:/ Drive)

Representing about 38 Go of space used

Site	Files	
CFL	Number	1 833 568
	Size (Go)	440,8
MLE	Number	150 896
	Size (Go)	38,4
VDR	Number	1 456
	Size (Go)	1,2
Bridgeway	Number	45 061
	Size (Go)	23
Toronto	Number	94 843
	Size (Go)	16
Total Number of documents		2 125 824
Total Size (Go)		518,7

Table-3: Number and size of files at different sites of IS.

Legend: CFL: Confluent (Lyon Head Office);

MLE: Marcy l'étoile (Lyon Industrial Site);

VDR: Val de Reuil (Paris Head Office)

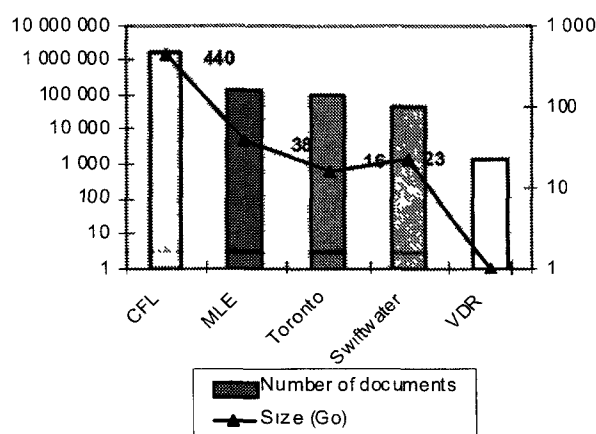


Figure-18: Number and size of files at different sites in shared folders of Sanofi Pasteur

Shared folder were limited to 700 Go authorized space depending upon the disc size. So it was considered important to archive some documents that were not in used.

Last access date

After discussion with the IS organization and *Accenture* consultant company, “last access date” was considered as the key process indicator (KPI) in order to know the frequency of documents in use. However, this KPI seems not to be consistent for Confluent and Marcy-l'étoile. It was lost by doing data migration with an application “RoboCopy”, which modified the access date. The values of the above graphs are presented in appendix I.

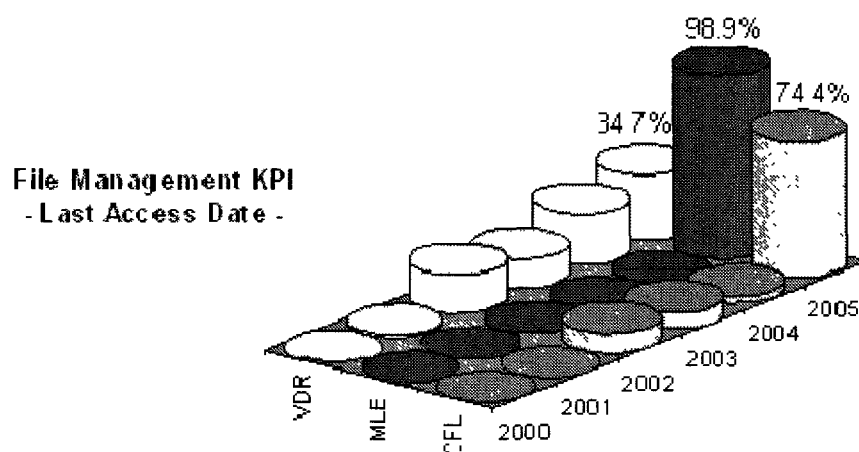


Figure -19: Number and size of files from KPI (last access date) for the last five years at different sites in France

Legend: CFL: Confluent (Lyon Head Office);

MLE: Marcy l'etoile (Lyon Industrial Site);

VDR: Val de Reuil (Paris Head Office)

The KPI 'Last Access Date' for North America (NA) seems not to be consistent for Toronto and Swiftwater. It was lost by doing data migration. The values of the above graphs are presented in appendix I.

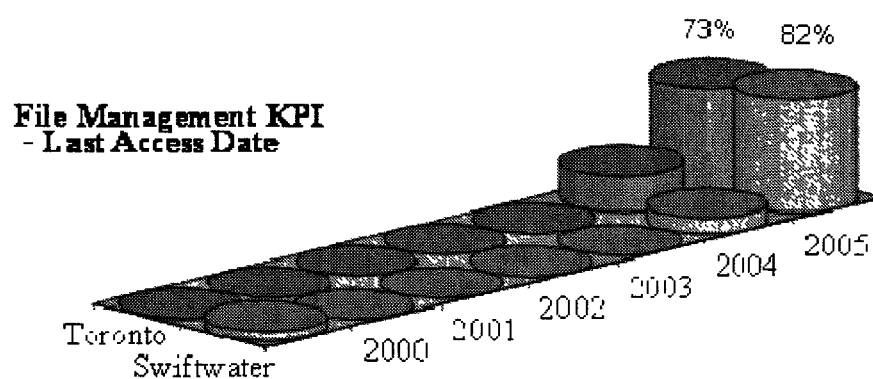


Figure-20: Number and size of files from KPI (last access date) for the last five years at different sites in North America

Access Date Assumption

The last access date for the site of Confluent and Marcy l'étoile was not traced, this made it difficult to analyze the case study. The last access date was available for the data concerning the Vale de Reuil site. It was assumed as having the same proportion for both of these sites which was based on the KPI for Val de Reuil site. The proportion for documents last access date for Val de Reuil was 65%, and could have around 65% of documents not used since 2004 representing around 300 Go for all French sites.

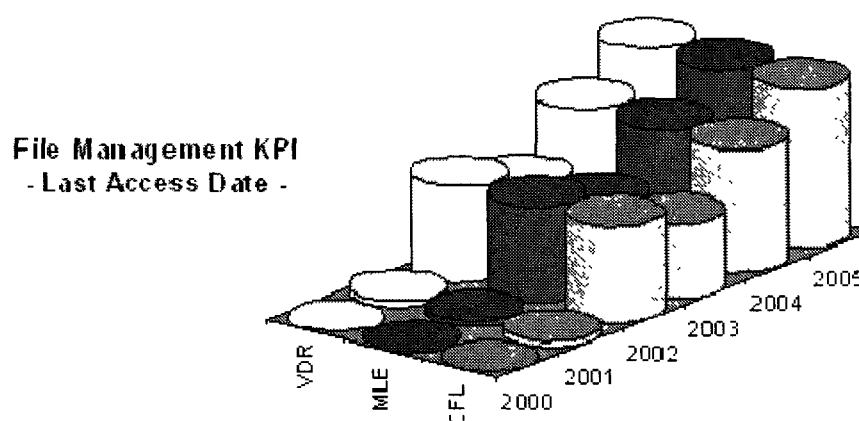


Figure-21: Documents last access date in France

Last date access was taken according to the date of VDR. All files were distributed according to the yearly percentage of VDR and then size was accordingly adjusted as presented below.

Site	Access							
		2000	2001	2002	2003	2004	2005	Total
CFL	2,0%	0,0%	0,0%	10,6%	8,7%	4,4%	74,4%	100,0%
MLE	0,8%	0,0%	0,0%	0,0%	0,0%	0,3%	98,9%	100,0%
VDR	0,0%	0,0%	1,4%	20,9%	16,0%	27,0%	34,7%	100,0%
Total Number	37 114	120	259	193 971	159 575	80 925	1 513 923	1 985 887
Total Size (Go)	14	0	0	17	17	41	391	481

Table-4: Number and size of files from KPI (last access date) for the last five years at different sites in France

Site	Access							
		2000	2001	2002	2003	2004	2005	Total
Swiftwater	6.7%	0.0%	0.0%	0.0%	0.0%	11.3%	82.0%	100.0%
Toronto	0.2%	0.0%	0.0%	0.1%	0.0%	26.0%	73.6%	100.0%
Total Number	3 243	47	15	126	2	29 676	106 693	139 802
Total Size (Go)	4534	2	0	14	0	2 820	30 937	38 307

Table-5: Number and size of files from KPI (last access date) for the last five years at different sites in North America

Site	Access							
		2000	2001	2002	2003	2004	2005	Total
CFL		0,0%	1,4%	20,9%	16,0%	27,0%	34,7%	100,0%
MLE		0,0%	1,4%	20,9%	16,0%	27,0%	34,7%	100,0%
VDR		0,0%	1,4%	20,9%	16,0%	27,0%	34,7%	100,0%
Total (Assumption)	0	0	27 297	414 921	318 015	536 394	689 260	1 985 887
Total Size (Lin.Approx.)			7	100	77	130	167	481
Total Number	37 114	120	259	193 971	159 575	80 925	1 513 923	1 985 887
Lin.Approx. size	9	0	0	47	39	20	367	481
Total Size (Go)	14	0	0	17	17	41	391	481

Table-6: Documents last date access since 2000 (via KPI: last date access)

Last Modified Date

The KPI 'Last Modified Date' shows that 86% of the documents have not been modified since the beginning of 2005. We could, therefore, consider them as reference documents because people did not access these documents. It was possible that people had another document source for some or many of these documents or those documents were not relevant for users.

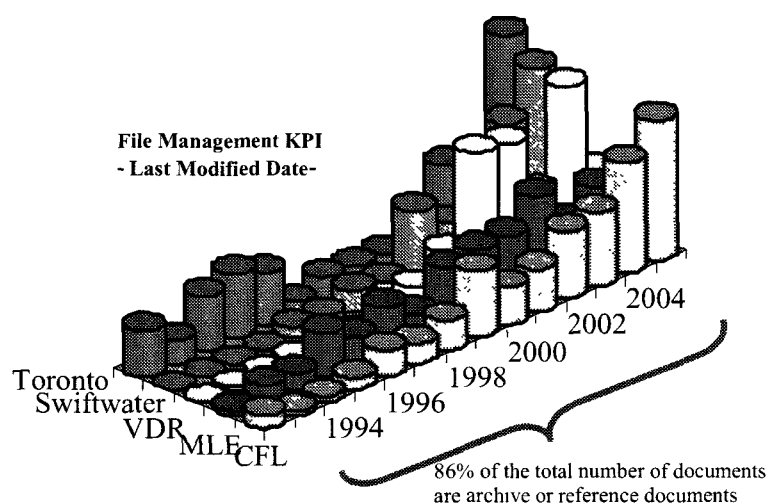


Figure-22: Documents last modified date since 1994 (last modified date)

2.3.4 Intranet

An intranet is a private computer network that uses Internet protocols, network connectivity, and telecommunication system to safely share part of an organization's information or operations with its employees. In short, an intranet can be called as "a private version of the Internet," or as a version of the internet confined to an organization.

2.4 IS Survey for file management

The table 1-4 presented the participant's location and their working nature

	Business	Infra.	Other	Platform	Quality	PMO	Total
Canada	3	5	2	4	2	0	16
France	31	12	4	18	5	1	71
US	18	18	10	7	3	1	57
Total	52	35	16	29	10	2	144
Percentage	36%	24%	11%	20%	7%	1%	100%

Table-7: Number of people participated in IS document management survey

Legend: Platform (Web, WISDOM, SAP);

Business (Industrial Operations, R & D, Commercial Operations, Support Function,);

Infrastructure (Customer Services, Network/Telecom, Database / Data Integration, System and Servers).

PMO: Project Management

2.4.4 Utilization of tools in the organization

People working in France and North America sites were asked about their utilization of these tools (shared folders, public folders, eRoom, Intranet, Personal

Folder, C Drive) with various types of documents. The file categories involved were the followings:

- **Policies / processes / procedures / forms:** Files describing rules, procedures or processes to determine decisions or actions; Forms to complete, to request or to deliver in a homogeneous way;
- **Project documentation:** Files related to an IS project including project budget, plan, requirements, etc.);
- **Applications:** Files related to an application implemented or supported by the IS department;
- **Technical items:** Files dedicated to a technical team or expert to assure the application's maintenance;
- **Communication:** Files to communicate and inform a wide range of people (IS); or a specific range of people (a team);
- **Team management/participation:** Files related to team management (budget, staff meeting minutes or similar document, objectives, planning activities, etc);
- **Vendor Info:** Files related to vendor (vendor highlights, new solutions presentation, etc.);
- **Planning / Calendars:** Files describing task or actions linked to a time frame;
- **Personal Files:** Files that are not ready to be shared and are related to a unique individual.

An interesting fact was revealed when file location analysis was done. It was found that the eRoom is the preferred tool used to store all categories of documents, except for supplier information and personal files. The “Documentum” tool was used in *Sanofi Pasteur* to store all quality procedures and policies

documentation. For this reason, the Documentum tool was not involved in the improvements plans and recommendations.

	Share d folder	Public Folder	e- Room	Intran et	Perso nal Folder	C Disk :	Out- Look Email	docum entum
Policies, Processes, Procedures, Forms (Methodology, etc.)			1 (52,6 %)		3 (34,5 %)			2 (47%)
Project documentation	3 (41,3 %)		1 (73%)		1 (48,4 %)			3 (42,6 %)
Application documentation	2 (44,5 %)		1 (56,3 %)		3 (38,7 %)			
Technical documents	3 (43,8 %)		1 (59,4 %)		2 (49,6 %)			
Communication documents			1 (56,5 %)		2 (42,6 %)		2 (40,7 %)	
Team management / Participation documentation			1 (66,1 %)		2 (42,1 %)	3 (39,7 %)		
Vendor general information			2 (46,2 %)		1 (49%)	3 (37,5 %)		
Planning / Calendars	3 (33,6 %)		1 (52,6 %)				2 (42,2 %)	
Personal documents					2 (61,8 %)	1 (69,9 %)	3 (29,3 %)	

Table-8: Response in terms of utilization of these tools

2.4.4.1 Best Practices observed in the IS

Various best practices were observed by participants in the IS which are mentioned in the following table 1-6.

1 Files organization / structure of the eRoom	101	24,8%
2 Sending links instead of documents to reduce documents copies	83	20,3%
3 WinZip	59	14,5%
4 Files organization / structure of the Shared Folders	52	12,7%
5 Documents nomenclature (Logical names)	34	8,3%
6 Files organization / structure of the Public Folders	33	8,1%
7 Regular file clean up (archiving & destruction)	24	5,9%
8 Other (Versionning, Documentum, .Pst, BdD eRoom)	14	3,4%
9 Files classification homogeneity between different supports	8	2,0%
Total Réponses	408	100,0%

Table-9: Best practices observed at IS for file management

2.4.4.2 Best file management practices to implement in the IS

1 A clear procedure on where to store files, when to archive, when to	130	27,9%
2 Clear / fixed hierarchy of documents	90	19,3%
3 Training & communications	89	19,1%
4 Indicators on space usage, files locations, etc	84	18,0%
5 Strict rules with few exceptions allowed	59	12,7%
6 Other	14	3,0%
Total Répondant	144	100%

Table-10: Best document management practices to implement

2.4.4.3 Know-how about file management practices

The next question was to know if the people were aware of the basic functions of these tools. So the question was if they know how to?

	Yes	No
Request a new share folder	X (72%)	
Archive Shared Folders documents		X (70%)
Request a new eroom	X (73%)	
Delete documents on erooms	X (82%)	
Archived eRoom documents		X (74%)
Archive e-mails	X (86%)	
Access your personal folder	X (81%)	

Table-11: Response to the question about using document management tools

Then people were asked about their knowledge on eRoom functionalities that can be described as:



Figure-23: Knowledge of eRoom functionalities

2.4.4.4 Suggestions proposed for file management

Various suggestions were proposed by members on file management in the survey. These suggestions can be classified as:

Table -12: Members' suggestions on file management

1-Archiving – (7/49)
▪ Good and constant communication on records retention requirements ▪ Promote email archiving
2-Catalogue – (4/49)

- Prompt the file owner every year to verify the list of files that has not been accessed for a certain period
- A single tool for all file management integrated into the desktop e.g. network sharing without a difficult-to-use web interface having an automatic archival to tape based on last access time
- Received once a year alert on old documents to classify, archive, those documents
- Being able to easily identify redundant files

3-Cleaning – (6/49)

- Declare file purge days allocate a special day half day every six months etc where we encourage people to reduce their network file storage provide prizes for the best percentage reduction
- A clear procedure that will eliminate redundant applications devices for storage and will notify users when cleanup is necessary
- Cleaning documents after each project is closed

4-File Structuring – (4/49)

- A clearer shared network folder hierarchy and naming rules and stricter access
- Impose a unique file structure and naming rules for US, CA and France

5-Location – (7/49)

- Reduce the number of choices where documents may be stored (project

wise, etc) ▪ Stop using Public & Shared Folders ▪ Clear rules on where to store documents
6-Process – (2/49)
▪ Draft version documents and temporarily store in clearly labeled folder in my documents / delete when documents finalized / store final document in clearly labeled network folder / archive or delete after project completion or in 2 years ▪ The implementation of a project management file structure must be put in place at the beginning of a project.
7-Roles – (6/49)
▪ A clear set of guidelines that are followed by all team members ▪ Clear directions and governance global transparency unless there is a issue with confidentiality ▪ Owner must be assigned on every file ▪ Use this opportunity to better assign user profile and level of confidentiality granted
8-Tools – (6/49)
▪ Compression tool for attachment / systematic use of zip ▪ Automatically archive old files to offline supports ▪ Search tool applicable on various supports

▪ Have a way to track relationships between documents a forward and backward traceability ▪ Have a system to scan the storage locations ▪ File owner being prompt to response to delete archive or active otherwise they will be prompted again ▪ Get a solution to have access to email attachments where they are saved on eRoom
9-Training / Communication – (3/49)
▪ Train people how to share files without sending them (links) ▪ Provide guidelines to help people to understand the policies and procedures about documents ▪ Train users on what kind of format they should save their files (e.g. jpg versus bmp)
10-Others
▪ Shared folders do not permit access between France and North America

2.4.4.5 Evaluation of IS good practices and Gaps

Based on the discussion with IS teams, various good practices and gaps were identified.

	Good Practices	Gaps
Processes	Structured process for new eRooms and Shared Folders creation There is a suggested files	Once eRooms and Shared folders are created, there is no specific structure to follow There are no files naming structure

	structure for eRooms that can be applied for other supports.	suggested No guidelines on where files should be stored Templates not broadly used eRoom request – creates eRoom but does not work with requestor to set it up to be efficient.
	There is a Records Retention Policy	Most people are not aware of any file Management Policy or <i>Sanofi Pasteur</i> 's best practices they should follow.
	NA Help Desk has a clear and regular process of file structure & cleaning	There is no clean up procedure (except NA Help Desk) to keep only important documents & facilitate file sharing
	Not long ago there has been a process of Personal Network Folders clean up – specific file types messages etc.	There is no specific archiving procedure for all files / support
		When people leave the company their email is not completely closed and they can still receive internal emails.
		There is no catalogue data on former employees receiving emails, people who has multiple copies of documents, executables, etc.
Roles	Identified person per team to take care of the Intranet	There is no specific person dedicated for file management (all IS or specific for each team).
	The Record retention policy describes the role of a record manager	This role is not clear for users neither who owns the role.
	People say they have the right profile to access specific documents	Information is segregated.
Tools	The eRoom search tool is appreciated	There is no efficient search tool for the entire network / Intranet / C drive
	Outlook storage capacity forced people to clean and structure properly. This limit requirement is understood.	

	Some people suggested this practice to be enlarged to other supports	
	People do not use public folders to store new files. They are mainly used for references, methodology, and shared calendars. Many people do not even know how to create new folders or put documents there.	
	Future migration to Outlook 2003 in 2006	The archiving Outlook tool does not meet people needs to structure their archiving emails and easily retrieval.
	eRooms features are very well appreciated like version tracking, notifications, databases, chats, etc.	People are not trained on eRooms features
Data Sharing	Intranet is used to publish information on services offered and required forms	Intranet is not used as knowledge repository accessible to everyone.
	Current/ongoing documents seems to be easy to find/access	Historical documents (project and others) seem to be more difficult to find.
Working Practices	Many people keep important working documents on their personal network folders as back up. Some people use the Personal network folder as a back up for their entire PC (including executables, etc.)	People in NA broadly use Documentum to approve documents and manage documents changes. People tend to keep various copies & versions on a working document on different supports.
	There is no destruction / archiving of old document versions not required for future use.	Some changes do not need another version name.
	People keep the same kind of files on different supports (each project, team can select a different support)	People tend to call and ask for a document to be sent to them when they either do not know its location or do not have access to it

Table-13: A list of good practices and gaps (category wise)

2.4.4.6 Suggestions for file locations

During these interviews, a majority of people suggested storing their documents likely for each kind of tool.

Reference Documents	e-Room	Shared folder	Intranet	Outlook Email	Other
Policies, Processes, Procedures, Forms (Methodology, etc.)			X		
Forms & templates			X		
Project documentation (including Project budget, Plan, Requirements, etc.)	X				
Applications documentation (specification, test scripts, etc)		NA			FR (c@pl is)
Training (users' manual, list of participants, facilitator guidelines, etc)	NA				FR
Technical items (including executables, databases scripts, etc.)		X			
IS General communications (IS announcements, news, etc.)			X		
IS Specific info (Presentations, press release, etc.)			X		
Team management/participation documentation (Budget, staff meeting minutes or similar document, objectives, planning activities, follow up)	X				
Vendor general info (vendor highlights, new solutions presentation, etc.)	X				
Vendor confidential information (Contracts, Service level agreements, etc.)	X				
Planning / calendars	X		X	X	
Personal documents		X			

Table-14: Suggestions in terms of utilization of these tools

Legend: Working and reference documents: W/R; Working documents: W;

Reference documents: R.

2.4.4.7 Recommendations for file management tools

After taking into account all the details (assessment of each tool, surveys and interviews with *IS* teams and advantages and disadvantages of each tool), various actions were suggested regarding the tools that were currently used for storing files which are the following:

Functional Criteria	Solution	Recommendations
Existing collaboration	Public Folders	Migrate file to new structure (in eRooms and Shared Folders) Close existing Public Folders
Information sharing	Shared folders	Keep shared folders, but only for application documents*, technical items and personal documents Rebuild file structures and migrate files Implement processes and tools for producing KPIs
Wide communication	Intranet	Confirm the Intranet usage: wide communication of reference documents
Collaboration and information sharing	eRoom	Use for all other kind of files Improve file structure according to recommendations Migrate documents to new structure Improve user eRoom knowledge (communication and training) Implement cleaning policies of an eRoom after completion of the topics for which the eRoom had been created

* Application document required on current project can be saved on eRoom

Table-15: Recommendations for IS file management tools according to the functional criteria.

Though some IS team members liked the structure proposed by their team individually for public folders, it was advised to close these folders because Microsoft had planned to stop supporting it from the year 2006.

Seventy percent of the allotted space was already used by IS teams working in France for shared folders. Though, with the help of key process indicator (KPI) that was last access date in this case, 86% percent of documents were classified as reference documents. Shared folders were advised to observe in the light of KPI to improve its utilization. It was also proposed to keep shared folders with the help of an improved file structure.

It was observed that 20 % of the eRooms used 80 % of the documents. *IS* teams admired the structure of eRoom in organizing their files. In file location analysis *Table-8* the eRoom was found to be among the most suggested tools. It was advised to use the eRoom for all sorts of files. One third of IS members indicated that they possessed only basic features of eRoom. Only one third of IS members were aware of advanced utilization of eRooms. It was recommended to provide training to the user in order to improve the utilization of its functions.

Intranet was considered as a way to communicate inside the organization.

Appendix 3: Volvo Powertrain

3.1 Introduction to Volvo Powertrain

Volvo Powertrain was the world largest manufacturer of heavy duty diesel engines of 10 litres and more. It had operations in Sweden, France and North and South America. *Volvo Powertrain* supplied the *Volvo Group* with diesel engines, transmission systems and axles. The driveline, which consisted of the engine, gearbox and the driveshaft or drive-shafts, was often described as the heart of a vehicle. *Volvo Powertrain* was responsible for the development and production of heavy engines, gearboxes and drive-shafts. *Volvo Powertrain* had more than 8000 employees in 2006.

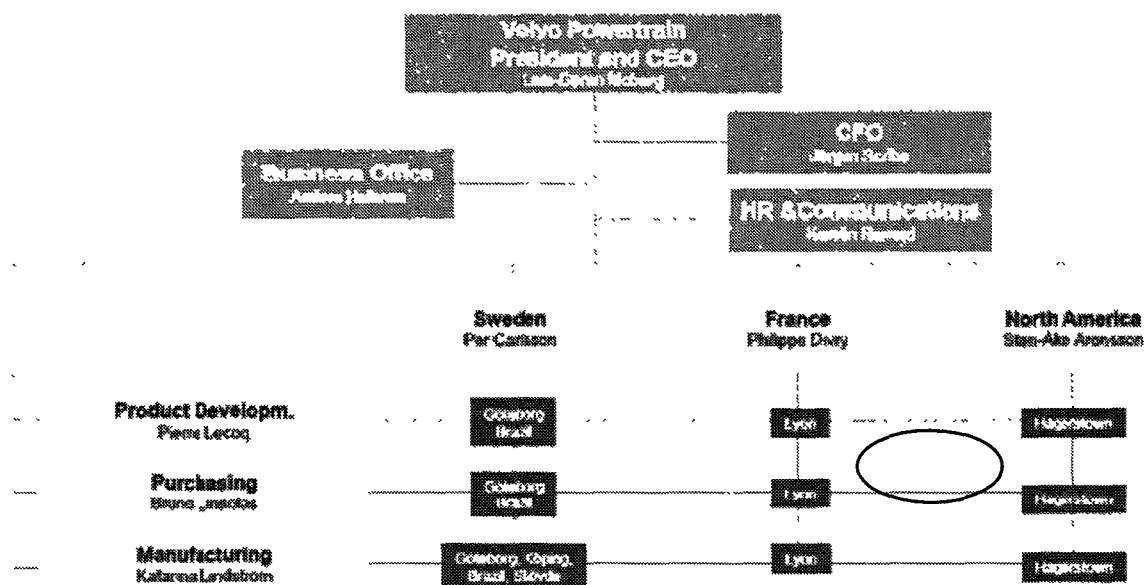


Figure-24: Organization of Volvo Powertrain in June 2007

Volvo Powertrain was composed of three branches: *Product development*, *Purchasing* and *Manufacturing*. *Product Development* was responsible for the engineering and design of engines, gearboxes and axles for *Volvo Group* customers with 1500 employees. *Volvo Powertrain* had three regional divisions (Sweden, France and in North America). The European road diesel engines from 3 to 11 litres were developed in Lyon, in addition to, 3, 5, 7, 9, and 11 litres engines. The American road diesel engines were developed in Hagerstown for the American market. The other engines and especially European road diesel engines of 13 and 16 liters were developed in Gothenburg.

3.2 Volvo Powertrain Structure

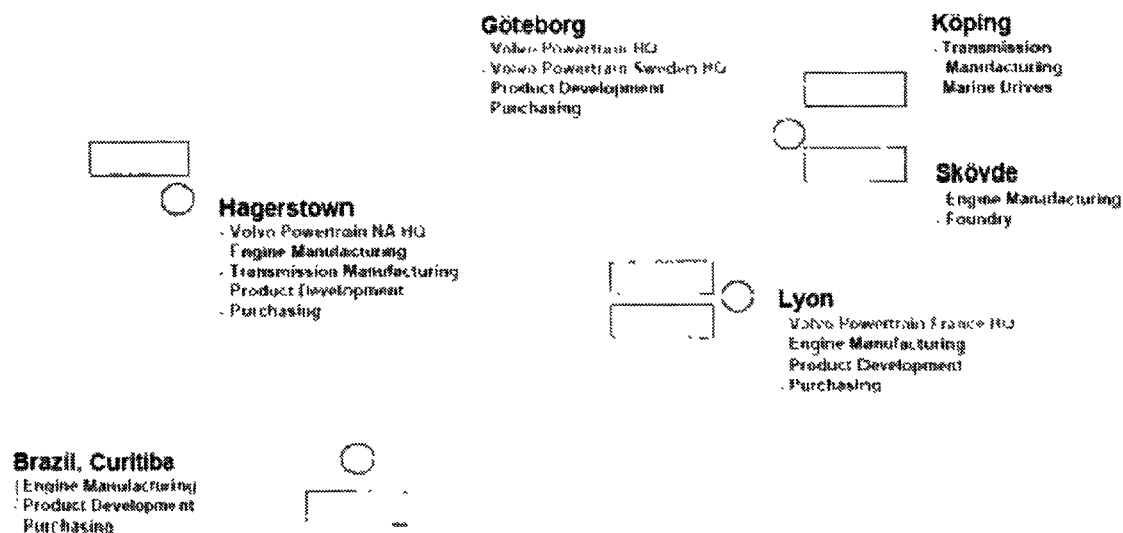


Figure-25: Volvo Powertrain Structure in the world

3.3 Volvo Powertrain Organization

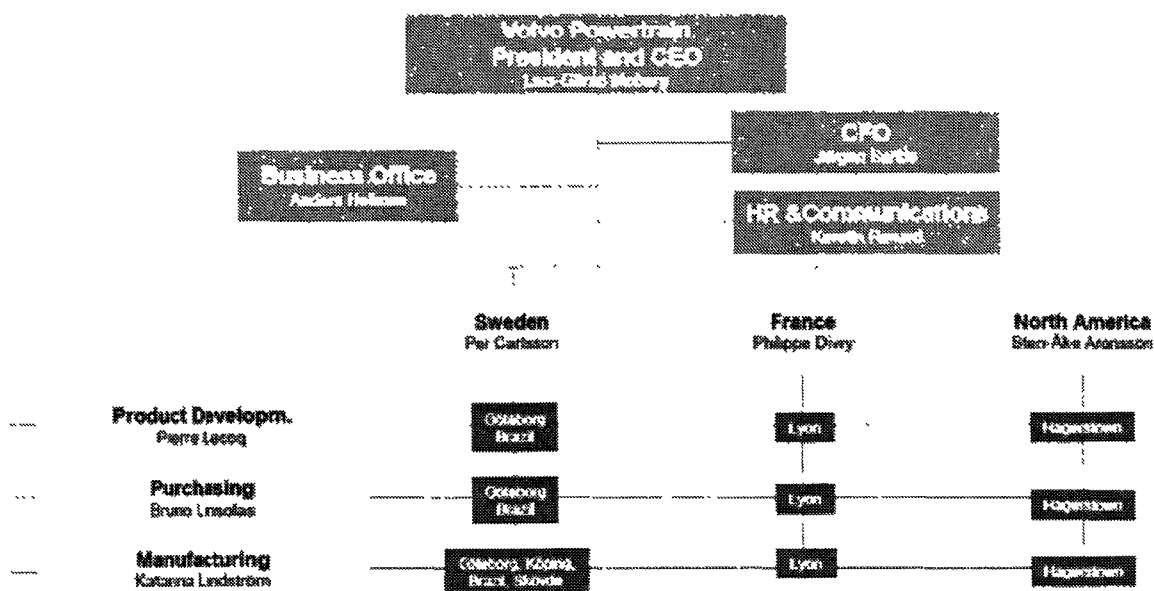


Figure-26: Volvo Powertrain organization in the world

3.4 Product Development (PD)

PD was to provide test facilities that correspond to engine requirements and driveline designs. The role of PD was to build the prototype and perform the relevant tests respecting QCD (Quality, Cost, and Delay) requirements. PD expects departments to carry out the desired engine tests to analyze their results. Some tests concerned the performance and durability which were internally created and used for engine development. Some tests included test codes that permit to establish the engine's installation conditions or common criteria that had to be respected while running a performance test. The organization flowchart of PD in France in June 2007 is presented in figure below.

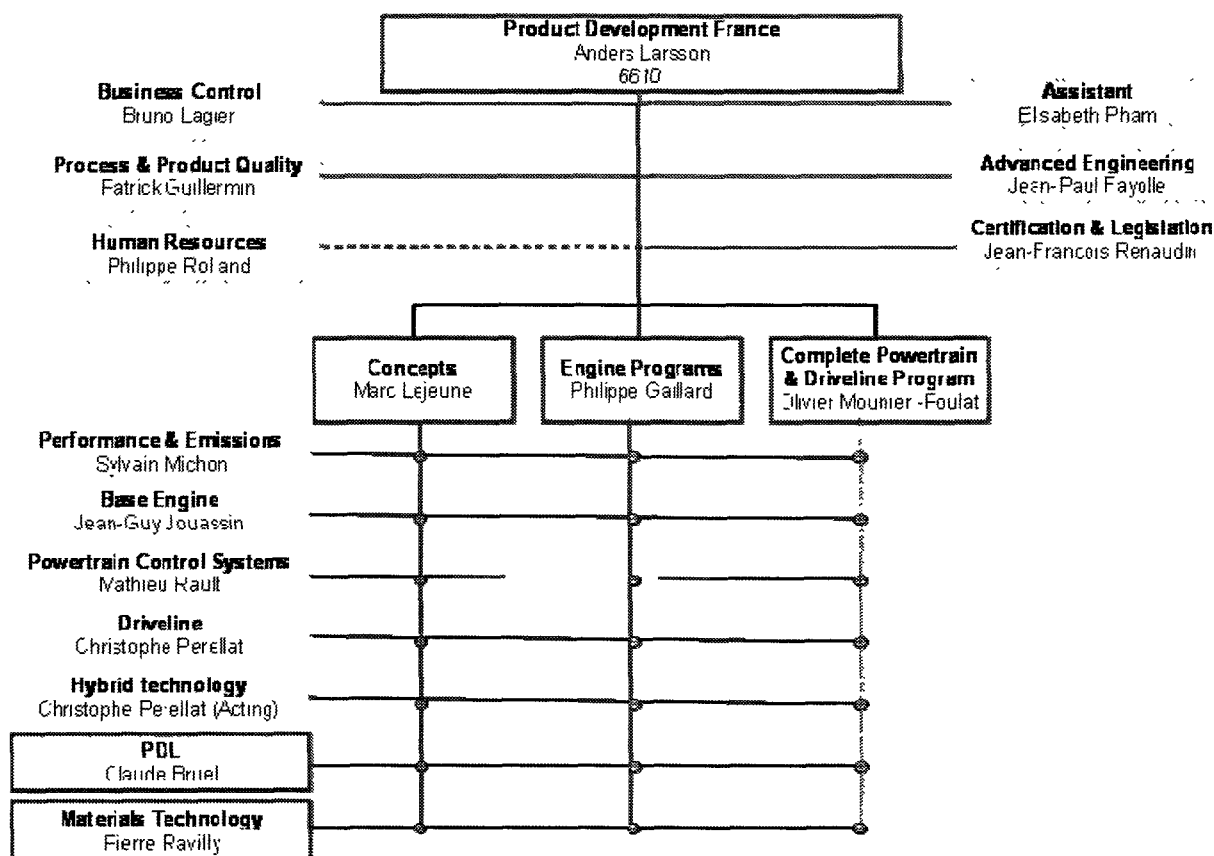


Figure-27: Organization of Product Development France

3.5 Engine Test centre Presentation

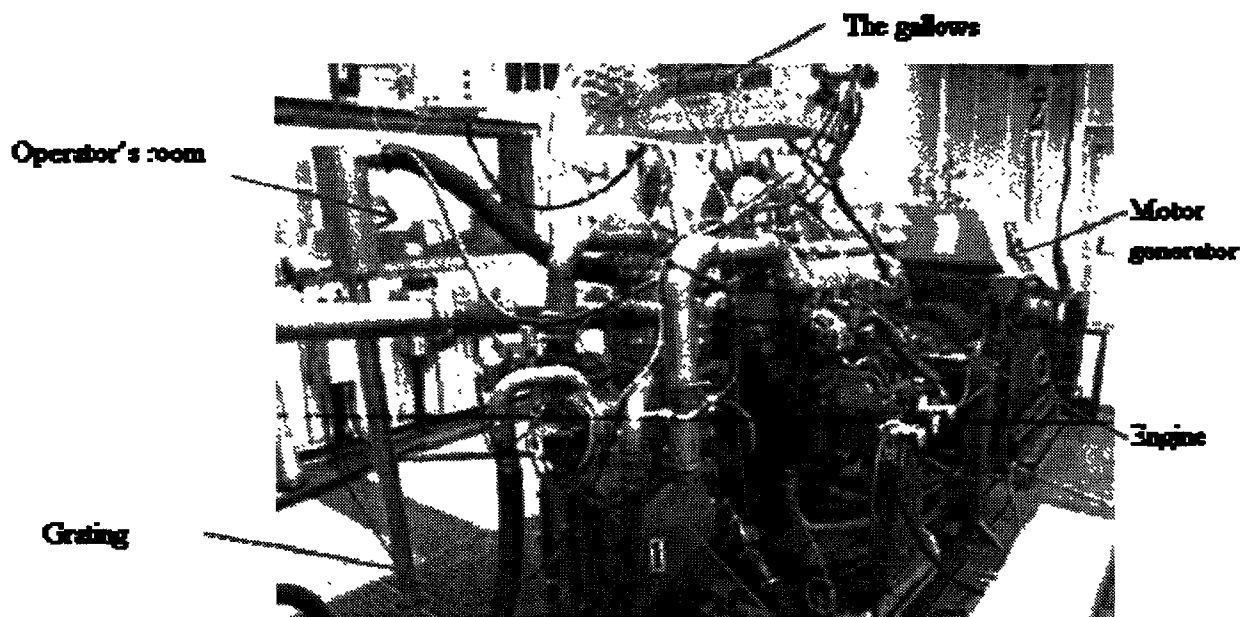


Figure-28: Presentation of an engine test centre of PDL Volvo Powertrain in Lyon

3.6 Process of work order of Coswin 7i (in French)

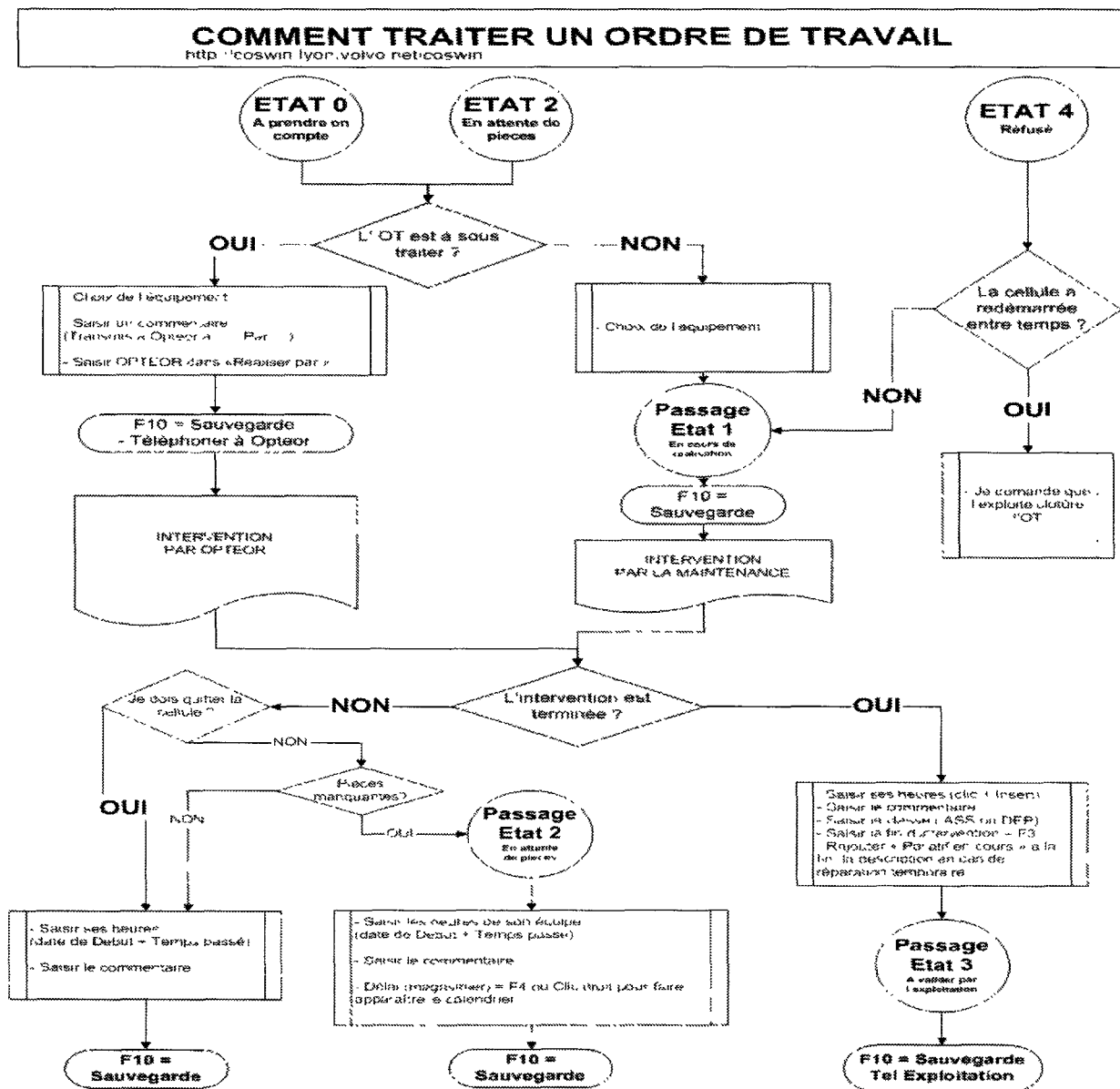


Figure-29: Work order process of Coswin 7i in PDL

3.7 An overview of yearly PM plan

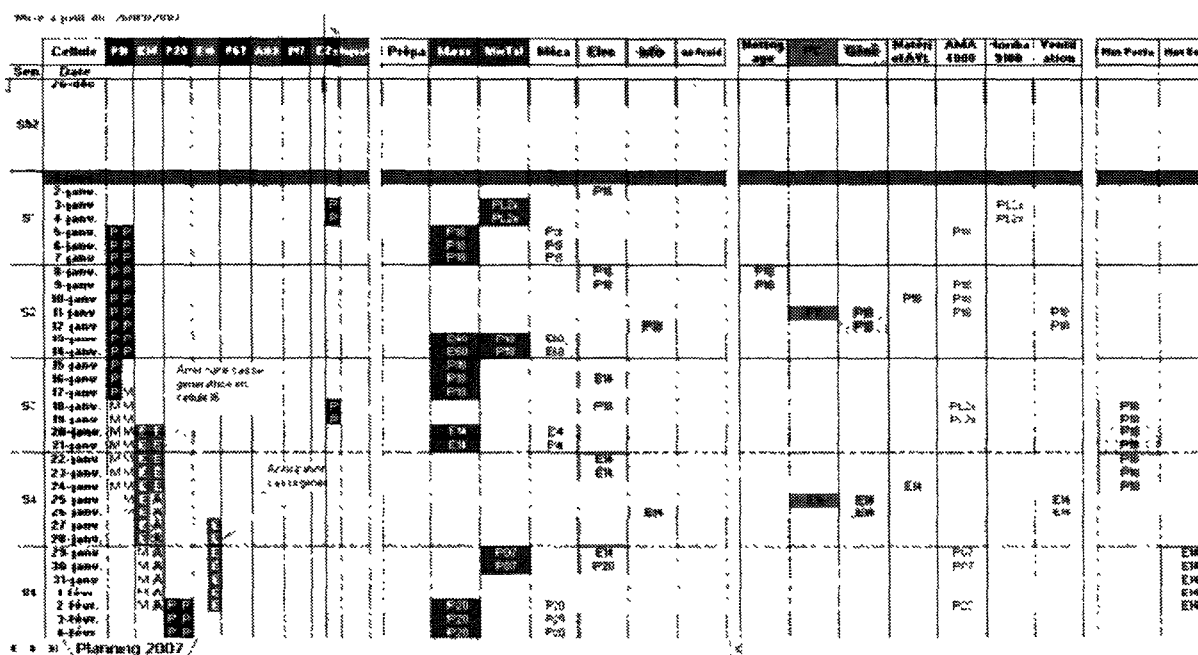
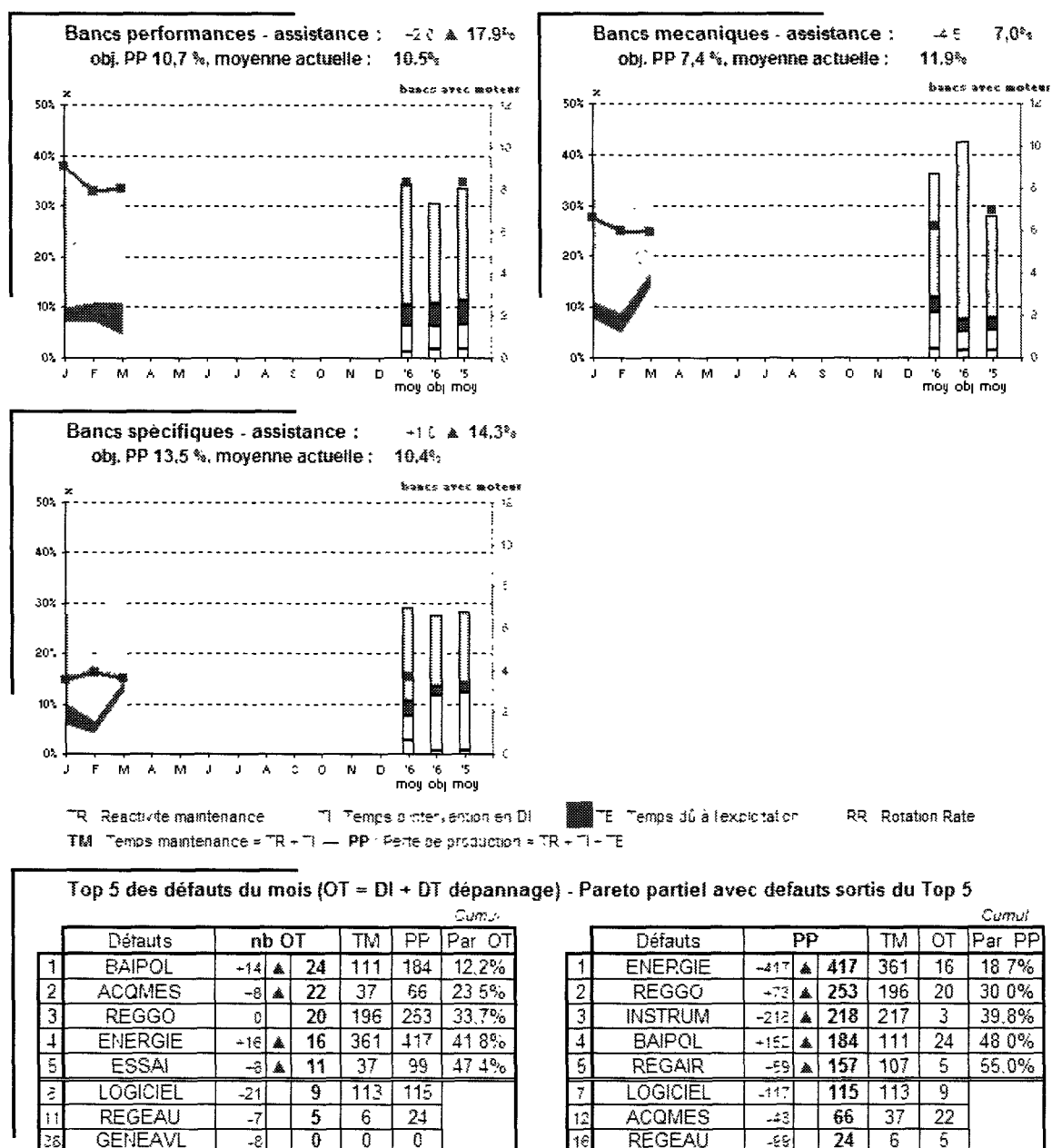


Figure-30: An overview of preventive maintenance for test centres is presented for the year 2007

3.8 An example of dash board of PDL Maintenance department



Plan d'actions - faits marquants

- ENERGIE : 417 heures de pertes de production liées aux projets TCI 24-26 (2 arrêts salle des eaux et un déclenchement incendie)
- REGGO : pannes essentiellement sur régulations conçues en interne
- INSTRUM : nouveau code destiné à suivre les pertes de production liées à l'instrumentation moteur (auparavant comptabilisées dans ACQMES)
- très haut niveau de panne en cellule 60 : 500 heures en mars (début d'incendie : cellule non standard appro de pièces spécifiques et moins bonne connaissance des systèmes)

Figure-31: An example of dash board of PDL Maintenance department to indicate some KPI (key performance indicator).

3.9 Maintenance management data for the equipments

	2006.01.02		2006.12.31		Pareto PP		
	PP	MTTR	nb OT	nb AS	% AS	MTBF	%
	k	k			%	days	%
1 Software test descriptions	3798.2	17.6	256	47	21.3%	1.4	14.9%
2 Emission benches	2707.8	12.1	275	22	9.3%	1.3	10.6%
3 Reg + Measure fuel	2378.6	17.5	148	9	6.5%	2.5	9.3%
4 AVL dynos	1871.4	41.7	50	5	11.1%	7.3	7.3%
5 Meas. simple acquisition	1697.4	13.6	157	14	11.2%	2.3	6.6%
6 Mech. engine auxiliaries	1573.8	30.3	63	3	5.3%	5.0	6.2%
7 Siemens dynos + Schenck	1469.3	29.4	66	1	2.0%	6.6	6.8%
8 Engine electronics	1328.1	21.8	74	13	31.1%	4.9	5.2%
9 Fuel sample system	1045.6	24.5	58	3	0.3%	6.3	4.1%
10 Eng. cooling regulation	793.9	11.0	86	7	9.7%	4.2	3.1%
11 Automates	739.8	61.6	16	1	6.3%	22.0	2.9%
12 Lab. control energies	699.8	25.2	33	4	16.7%	11.0	2.7%
13 Software	646.2	10.0	00	9	3.0%	4.0	2.5%
14 Eng. air admission regulation	467.4	7.7	72	2	3.3%	5.1	1.0%
15 Urea	423.1	16.2	31	3	11.5%	11.7	1.7%

Figure-32: Data for the equipments with higher production loss (PP) with the number of work orders (nb OT), assistance (AS), mean time between failures (MTBF) and mean time to repair (MTTR) in 2006.

3.10 Pareto chart for operational maintenance for 2005

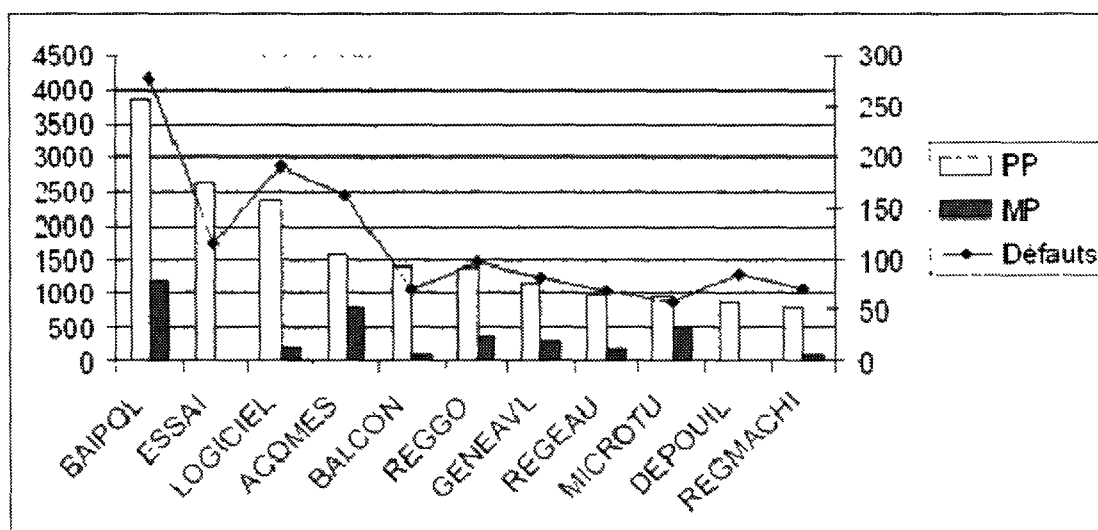


Figure-33: Pareto chart for operational maintenance done with preventive maintenance and number of work orders for 2005.

Appendix 4: A list of the major participants in discussion for QM activities

Number of People	Working department	Position in Case Organizations
1	Production	Senior Vice President
1	Assembly	Coordinator Engine Assembly
1	Assembly	Manager Assembly
1	Quality	Manager Quality
1	Quality	Quality Specialist Engine Assembly
1	Quality	Quality Engineer
1	Engine Assembly Shop	Assistant Manager
3	Engine Assembly Shop	Group Leaders
12	Engine Assembly Shop	Team Leader
78	Engine Assembly Shop	Team Member
1	University	Ph.D. Researcher
11	Quality	Industry Quality Specialist
25	Maintenance Department	Team Member
1	Maintenance Department	Director Maintenance
2	Maintenance Department	Manager Maintenance
5	Laboratory Development Group	Development Engineer
1	Engine Driveline & Testing Operation (ETO)	Director ETO
3	Engine Driveline & Testing Operation (ETO)	Manager ETO

1	Quality & Validation	Director
2	Quality & Validation	Deputy Director
4	Quality & Validation	Quality Analyst
3	Quality & Validation	Validation Analyst
1	Project Management	Project Engineer
1	Data Security	Chief Security Officer
1	Department of Nuclear Energy and Safety, Switzerland	Research Scientist

Appendix 5: Assessment instrument for QM elements, QM implementation and awareness culture

An assessment instrument was built up to measure the QM implementation and practices. The tool was based on the elements used in the model to evaluate and identify weaker areas. The instrument is actually the transformation of QM components, implementation practices into core activities. The assessment instrument enables an organization to quickly distinguish weaker and stronger areas of the organization and can assist in evaluation of the QM implementation process. With the help of this tool, organizations can focus on the weaker areas that require improvements. The next paragraphs provide the working of the assessment instrument and its usage to evaluate and measure the organization's QM advancement in a time frame.

This assessment instrument provided here can be used to assess QM elements, QM implementation and quality level in an organization. The first table deals with assessment of quality level in the organization. The first column lists the quality level achieved in QM element and implementation practices. The second column lists the quality level in terms of progress and the third column lists the addressed area for each practice. Third column presents the grading criteria with the help of a situation presentation, which seems to be helpful for any investigator to evaluate the organization's QM level between initial (level 1), and optimized (level 5). The lower rating quality level for implementation requires more work care to improve its quality level. Level three is considered to be a

minimum requirement to remain standardized in QM level, element and implementation practice. The first quality level indicates that the organization has just started with a very basic level of quality practices and is considered to be at the “initial” stage. On the other hand, the fifth quality level means that the organization has well established a high quality level of quality practices being adapted and is considered to be at the “optimizing” stage in the quality level definition. The instrument developed mentioned here to define this rating level of quality maturity, with each QM element and QM implementation phases, grading rules and guidelines were developed with the help of various resources including quality award models including the *European Model for Total Quality Management* (1994), the *American Malcolm Baldrige National Quality Award* (1999), [402] and *Capability Maturity Model Integration* [70] [71]. The assessment instrument to measure the quality level in an organization is presented below.

Level	Implementation	Criteria
1	Initial	Chaotic implementation (hero worship) Ad Hoc, rough and occasionally disorder evidence is available; Chaotic processes and approach existed to the necessary purpose of the practice which depends on individuals managing; Considerable variations are visible in implementation, no repeatable process in place which inhibits advancement in accomplishing the basic purposes of the practice.
2	Repeatable	Marginal implementation (reduced rework and overload) Basic necessary evidence is available to repeat earlier and mainly based on reactive management; - Few of the areas follow the quality implementation stage. - Lack of historical information to fully adopt the systematic approach to the practice adopted for some time.
3	Managed	- Adequate implementation (productivity growth) - Enough asked evidence is available with well defined and approved processes through measurement history;

		- An approach is well instrumented and systematic, which is consistent for the overall purposes of the practice; - The approach is a tailored standard with low variability in implementation in some areas.
4	Standardized	Good to excellent implementation (predictable results) - All necessary evidence is available in details in a systematic approach; - An approach is systematic and soundly based, which is understood, measured and controlled for multiple requirements of the practice; - The approach is well implemented without significant gaps.
5	Optimized	State of the art implementation (achieve targets) - A sound, innovative approach, proactively monitored, fully responsive to all the requirements of the practice is fully developed; - Continuous improvement enabled by demonstrated feedback - The approach is fully implemented without significant weaknesses in any area.

Table -16: Scoring guidelines for QM implementation

Each level can be considered as a well-defined stage in order to acquire quality. To acquire the next quality level, there is a need to improve and follow a set of improved activities and steps that describes a growth path to a higher level. Lower quality level indicates that the organization does not have well defined processes for the implementation of QMS. Keeping in view this point, it is considered that higher the degree of quality level an organization has, more it contributes to successful implementation. Lower is the level of quality achieved by an organization, higher is the risk associated in terms of implementing the QMS.

The assessment tool presented in table 18 can be used to measure and assess QM elements in an organization. The first column lists the quality level achieved in deploying QM elements. This level should be measured in the direction provided by Table 17. The second column lists the QM dimension or elements which are discussed in our QM model. The third column lists the addressed area for each element through several practices. The third column presents the grading

criteria with the help of a situation presentation, which seems to be helpful for any investigator to evaluate the organization's QM elements functioning between initial (level 1), and optimized (level 5). Thus, assessment of the organization's QM element employing the ranking level between "1" and "5" is possible. During the process of assessment, the strengths and weaknesses of addressed areas should be pointed out. If the organization is neither stronger nor weaker in an addressed area, "Standardized" with level "3" should be mentioned. The strengths and weaknesses provide the ground to prepare the action plans for improvements. Establishment of improvement plans can be proposed once the identification of the weaker areas of the organization's QM implementation is done. In case if any QM element seems not to be applicable, then the quality element level should be replaced with "not applicable" in the rating column. As stressed by all quality experts, quality awards, and the literature survey, evidences should be measured in defining the quality rather than imagination [402]. The assessment instrument to measure the QM elements in an organization is presented below.

Level	QM Construct	Quality practices
1-5	Top management - Commitment, participation, learning, encouragement, fact management	- Strong commitment to strategic quality planning and continuous improvement on regular basis; - Commitment to quality through actions; - Conduct, participate and access QM implementation personally; - Interact, communicate and listen to employees; - Go for management education and training; - Conduct training lectures to employees and create a learning environment; - Promote employees participation in QM activities; - Create an open dialogue with employees and conceive employees' suggestions; - Respect employees and help them using the organization system in a trustworthy environment. Back up employees in order to boost their moral; - Concentrate on quality in process, product and service; - Engage in long-term business performance. - Take decisions always on the basis of reality and facts

		by using relevant information; - Decision making involves various source of information.
1-5	Personnel - Training and learning - Participation and involvement	- An effective ongoing training and learning plan is established according to the employees' requirements and the organization's resources; - Adequate resources are provided to deploy the training and learning program; - Employees are appreciated for their suggestion and provide them with feedback evaluation and deployment of useful ones and support the suggestion providers; - Encourage quality information sharing and availability among employees; - Focus on quality culture development through awareness and provide employees training on quality concepts and standards; - Use of quality control tools through proper training; - Employees are offered adequate job training which suits their job requirements; - Rotate employee jobs regularly to make them versatile; - Respect, trust, and encourage employees to discuss and describe their working problems; - Provision of quality working environment (tools, devices, equipments) with safety measures; - Share organization information regularly and communicate effectively inside and outside teams.
1-5	Strategic quality planning - Quality policy and planning - Business performance strategy - Improvement plan	- Well define quality policy with a long-term strategic quality planning; - Convey the quality policy and planning to all employees in order to integrate in achieving quality objectives and for business strategies; - Prepare and communicate quality improvement plans addressing vital problem areas and provide global action for implementation in daily practice; - Employ quality information to develop the strategic plans involving employees from various levels; - Build the strategic plans and associated practices in a uniform way.
1-5	Processes	- Measure, control and improve process capability;

	Management - Capability - Maintenance - Inventory management - Review and Innovation - Quality tools - 5 S	- The process is managed systematically and is responsive to the overall purposes of the practice; - Equipments are regularly undergo under maintenance (corrective, preventive, predictive); -Involve employees in introducing production equipment that satisfy their production requirements. - Conduct effective audits and inspection in all areas to provide innovative ideas for improvement; - Conduct random sampling inspection to seek quality improvement; - Minimize inventory as little as possible and keep in good order; - Utilize and implement quality tools and PDCA cycle for various activities extensively; - Use 5S to keep the areas always neat and clean, well managed, without any waste item; - Ergonomics is applied to all work place (light, temperature, noise, air).
1-5	Customer Orientation - Customer information system - Customer services (quality warranty, satisfaction survey; complaint system) - Dialogue with customer (Internal customer orientation was only considered)	- Register customer complaint and use this information extensively to treat and rectify the complaint. - Customer complaints should be given first preference with appropriate solutions and propose improvement actions after analysis; - Develop efficient customer satisfaction measurements by collecting information (concerning their satisfaction requirements, potential needs and expectation) to provide quality improvements plans; - Offer a quality warranty on all provided products; - Establish an effective customer information system and use to prepare customer focus strategy; - Establish multiple communication channels with customer.
1-5	Supplier Management - Supplier selection	- Obtain sufficient information about suppliers or potential suppliers; - Understand suppliers' facilities and production capabilities;

	criteria - Partnership with supplier (performance evaluation, quality audit, communication)	- Select supplier based on the quality of products and services rather than price alone; - Work conjointly with suppliers by considering as partners and pursue long-term stable business relationships; - Provide trainings, participate supplier quality improvements projects; - Evaluate the performance of products and services, provide feed back with grading in terms of product quality and service quality from supplier performance evaluation system for measuring suppliers' performance; - Conduct supplier quality audits of QMS, products and services, facilities regularly; - Feedback from and to suppliers of any change in design and /or production immediately; - Establish multiple channels of communication with suppliers.
1-5	Information and Communication - Information system	- Provide sufficient information to employees regularly (meetings, posters, newsletters, videos, and broadcasting); - Have effective information communication among different departments; - Stimulate mutual communication among people at different levels; - Have a computer-based integrated information system with sufficient information in the system; - Collect and share information among different departments; - Use the information system extensively for various business activities.

Table-17: QM implementation dealing areas with attained quality level

The assessment tool presented in above table 19 can be used to measure and assess QM implementation phases in an organization. The first column lists the quality level achieved in implementing QM phases. This level should be measured in the direction provided by table 17. The second column lists the QM implementation phases which are discussed in our QM implementation model. The third column lists the addressed area for each implementation phase through the areas dealt with. The third column presents the grading criteria with the help of

situation presentation, which seems to be helpful for any investigator to evaluate the organization's QM implementation phase functioning between initial (level 1), and optimized (level 5). The assessment instrument to measure the QM implementation phases in an organization is presented below.

Level	QM Implementation Phases	QM practices
1-5	Quality Integration - Assimilation - Internally integrated and externally coordinated and adapted	- Responsibility and authority to coordinate common quality vocabulary and language are well defined; - All organizational practices are articulated according to the proposed QMS to implement; - Employees are involved in quality procedures and operational environments; - All employees have the same perception of QM on basic rules; - Organization business is synchronized (integrate, coordinate, adapt) with QM; - Common quality vocabulary is used extensively; - Employees are well informed about their job environment in terms of quality.
1-5	Quality Daily Use - Practice in everyday routine - Ways to improve	- Procedures created for the purpose of QMS are used in daily practice; - Preparation for external audit is not required at the last moment; - System is not considered as a burden and never ignored; - System is a part of routine activities; - System is a springboard to introduce new practices; - System is the starting point for other advanced practices; - System led to discovery of improvement opportunities; - A catalyst for rethinking the way the things are going on; - Understood as an opportunity to innovate.
1-5	Quality Evaluation - Assessment,	- Have an effective assessment system to measure the difference between actual performance and the desired one; - Provide ways to ensure greater control of performance

	audits - Control - Maintenance and assurance - Improvement - Departments' evaluation - Quality cost	and reduced deviation; - Assessment of QMS to identify improvement areas and strategies adapted and adjustment according to the requirements. - Remove non conformities found in evaluation process and formulate improvement actions; - Provision of actions to ensure that the system is maintained, and evaluate system on a regular basis; - Ensure the desire state both in design and use by accessing efficiency and provide training and learning to acquire; - System is deployed towards continuous improvement plans after evaluation. - Gather information and data on people, process, product, customer, supplier, business performance and formulate improvement actions according to the quality evaluation; - Have relevant information of market and benchmark the world class organizations; - Communicate quality evaluation results and work on improvements on regular basis.

Table -18: QM implementation phases through quality awareness

Index

5S, 166

Advantages of ISO 9000, 118, 119

Change management process, 137, 141, 145

Communication in organizations, 65-67

Communication-to-inform process, 74, 185, 248, 292, 343

Computerized Maintenance Management System, 271

Computerized system validation, 125, 131, 227

Computerized System, 127

Corrective maintenance, 280

Critics of ISO 9000, 121

Customer focus, 95, 183, 291, 342

Employee's Training, 90, 136, 182, 246, 288, 339

Engine assembly line, 161

Environment Management System, 169

Everyday use of quality, 190, 252, 297, 355

External communication, 71

Failure Mode and Effect and Cause Analysis, 275

File management, 228

Implementing ISO 9000, 116

Information Solutions Quality & Validation, 222, 222, 223

Information Solutions, 219, 221

Internal communication, 68

ISO 9000 certification, 105

Jidoka, 165

Job Element sheet, 166

Just in time, 163

Kaizen, 166

Kanban, 163

Maintenance department, 269, 270, 279

Model for QM elements, 344

Model Formulation for QMI phases, 361

Organizational Culture, 77

Participation and involvement, 93

PDL test centres, 266

PokaYoké, 165

Preventive maintenance, 281

Processes Management, 99, 184, 247, 289, 341

Product Development Laboratory, 265, 266

Quality awareness culture, 347-350, 352

Quality system evaluation phase, 191, 253, 298, 352

Quality integration phase, 188, 250, 295, 352

Quality management implementation, 188, 250, 295, 346, 352

Quality Management, 85

Quality, 84, 85

Role of communication in QM, 72

Strategic quality planning, 97, 180, 245, 287, 340

Top management, 88, 179, 244, 286, 338

Total quality management, 86

Toyota Motor Manufacturing France, 157

Toyota Production System, 163

Comprendre le rôle de l'information et de la communication dans le passage des techniques de gestion industrielle à une culture de la qualité: QMI (Implémentation du Management Qualité) dans trois entreprises multinationales

Résumé : Force est de constater que le rôle de la communication est souvent délaissé dans les programmes de management de la qualité en industrie, et ce malgré un discours prônant l'importance des échanges interpersonnels. L'objectif de cette recherche est de proposer un modèle qui met l'accent sur la mise en place du management de la qualité et s'inscrit étroitement dans un dispositif communicationnel. Pour ce faire, une approche semi-qualitative examine, à partir de plusieurs cas d'études, la manière dont trois organisations multinationales ont mis en place leurs systèmes qualité. L'étude fait ressortir les deux constats clés suivants. Premièrement, les procédures qualité sont sous-appliquées dans la pratique quotidienne du personnel de l'entreprise. Deuxièmement, ces procédures s'avèrent, néanmoins, utiles lorsque les employés doivent préparer l'entreprise à des audits qualité. Face à ce constat, le défi à l'égard du concept de QMI (*Quality Management Implementation*, c'est-à-dire le processus d'accompagnement du changement) est double ; nécessité d'adapter le management de la qualité à un contexte évolutif donné, ce qui exige l'ajustement continu des relations entre la direction et les employés - de manière à aider ces derniers à s'intégrer, comme catalyseur du changement, dans le système qualité de façon quotidienne. En conclusion, le modèle de QMI développé offre un cadre à l'implémentation ; il permet de gérer de manière plus pertinente les normes de qualité, dont la mise en place est indissociable de la communication aux moments opportuns dans l'environnement industriel.

Mot Clés: Qualité, communication-pour-informer, mise en place de système qualité, prise en conscience de culture qualité, ISO 9001, validation de système informatisée, ingénierie de la maintenance.

Understanding the role of information and communication when moving from industrial management techniques to a quality culture: QMI (Quality Management Implementation) in three multinational organizations

Abstract: Despite declarations about the importance of interpersonal exchanges, one can but note the neglected role of communication in industrial quality management programs. Given this, the thesis puts forward a model that focuses on Quality Management Implementation (QMI) as a response to this apparent neglect. To do this, the research adopts a semi-qualitative, case study approach in examining the way in which three multinational organizations implement quality management practices. The results highlight two key observations. Firstly, employees of the organizations under-apply quality procedures in their everyday use. Secondly, these procedures appear useful when employees have to prepare for quality audits. In this light, a twofold challenge emerges concerning the concept of QMI, *i.e.* the change process. On the one hand, there is the necessity for adapting quality management to a continually evolving industrial context. On the other hand, it is vital that management-employees relations be constantly adjusted to integrate employees in daily quality related operations as catalyst of change. In short, the proposed QMI model of this study offers an alternative way to manage quality standards as being connected to timely communication within the industrial context.

Keywords: Quality, communication-to-inform, quality management implementation, quality awareness culture, ISO 9001, computerized system validation, change management, maintenance management.

Industrial case study organizations: *Toyota Motor Company, Sanofi-Aventis, Volvo AB*