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► To cite this version:

Marie-Hélène Gentil, Catherine Merle. The use of quality tools, concepts and methods to help the transition to Industry 4.0: On the way to Quality 4.0. MQDS -INTERNATIONAL CONGRESS ON MEASUREMENT, QUALITY AND DATA SCIENCE, Jun 2023, Bordeaux, France. hal-04465176

HAL Id: hal-04465176

<https://hal.science/hal-04465176>

Submitted on 20 Feb 2024

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The use of quality tools, concepts and methods to help the transition to Industry 4.0: On the way to Quality 4.0

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ABSTRACT: Quality is a key element in any company regardless of its sector of activity, location and size. It can be defined as the ability of a product or service to meet customer expectations and needs as well as legal and regulatory requirements. Quality can also be seen as a differentiating factor for the company and can help strengthen its reputation and credibility with customers and more generally with stakeholders. To achieve this, companies implement quality management systems, methods, tools and standards in order to ensure that products and services meet specified requirements. The enterprise 4.0 is a company that uses new technologies in an innovative and integrated way to improve its performance, flexibility and competitiveness. Enterprise 4.0 relies on advanced technologies such as artificial intelligence (AI), internet of things (IoT), advanced robotics, digital twins and simulation to optimize its production and management processes. The objective of this communication is firstly to analyse and assess the contributions and obstacles between Quality and Enterprise 4.0. Our aim is to set out some principles/advice in order to allow a relevant articulation between these two approaches. In our communication, we will also outline the new tasks of the quality manager to pilot this quality 4.0. Then we propose the first constituent elements of an explainable AI to facilitate the management of the quality in the process of transition to enterprise 4.0.

Keywords: Enterprise 4.0 - Quality 4.0 - Explainable artificial intelligence (AI)

Received January 1, 2023; **In final form** March 31, 2023; **Published** June 2023

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1. INTRODUCTION

The term "Enterprise 4.0" was first introduced in 2011 when it was mentioned in Germany following a discussion at a forum in Hannover [1]. The same concepts can be found under the similar names of Future Industry, Industry 4.0 and Smart Factory ([2], [3], [4]).

Enterprise 4.0 is based on the use of technologies such as the Internet of Things (IoT) and its enterprise version (IIoT), artificial intelligence (AI), robotics, augmented reality (AR) and virtual reality (VR), the cloud, big data analytics, digital twins, data analysis, automation and connectivity between machines and systems. ([5], [6]).

These new technologies promote immediacy, speed and customisation of products. However, with Enterprise 4.0, everything is accelerating and the risks of errors and non-conformity are increasing: quality is becoming critical.

At the same time, the notion of quality is linked to the ability of a company to produce goods or services that meet the expectations of customers and stakeholders and comply with applicable standards and regulations. Quality can be defined as the set of characteristics of a product or service that enable it to meet requirements [7].

To manage quality, companies implement quality systems or quality management systems at all levels of the company (marketing, purchasing, production, delivery, management, maintenance, human resources department, etc.) using different tools and methodologies such as the process approach of the ISO 9001:2015 standard [8] and Six Sigma [9].

These two themes "Quality" and "Enterprise 4.0" have some similarities:

- a) Both approaches aim to improve the performance of the company by optimizing its processes to satisfy its customers and its stakeholders.
- b) Both approaches can use technologies 4.0 to optimize processes.

However, their articulation needs to be characterised.

The new technologies promise to solve the company's problems in terms of quality, speed and flexibility. Will quality management activities cease with the arrival of new technologies in the company [10]?

It is important to study how companies will manage the inevitable arrival of new technologies in the context of a transition to Enterprise 4.0 ([11], [12]) and the indispensable need to always guarantee the satisfaction of all requirements for the

sustainability and resilience of companies.

To achieve this, our paper will be divided into 3 parts. The first part (section 2) will first clarify the activities, tools and difficulties encountered in the framework of a Quality approach, then the difficulties encountered by the introduction of new technologies in companies. In the second part (section 3), we will discuss the notions of quality 4.0, the necessary changes in the missions of quality specialists and then we will establish the first components of an AI specific to Quality activities. Finally, the last section (section 4) will allow us to consider new areas of improvement and limits of the research.

2. METHODS

In order to study this articulation, the main quality activities carried out within companies, the tools and techniques ([13], [14]) used to implement these activities, and finally the available technologies 4.0 were listed. Table 5 briefly defines the tools mentioned. These different items were then classified according to the three strategic, organisational and operational levels of the company. This decomposition, based on the principles of systemic analysis ([15], [16]), gives us both a global vision of Enterprise 4.0 and a more detailed vision in processes/projects and activities. The result is presented in section 2.1.

The quality activities listed in these three tables are classic activities that can be found in most companies that have implemented quality systems such as those built based on ISO 9001 standards.

We recall that the ISO 9001 standard is an international quality management standard that defines the requirements for a quality management system. It was written to be used in any industry and in companies of any size. It aims to help these companies to improve their performance by implementing effective processes. To do this, it allows the implementation of a quality management system through the establishment of a quality policy associated with quality objectives that will then be declined within the identified processes. It is important to understand that this ISO 9001 standard is a standard that includes requirements of results and not of means. This means that companies can use new technologies to meet the requirements of the standard if they wish.

In parallel, the main problems encountered in quality systems and in the introduction of

technologies 4.0 were also listed. The results are presented in sections 2.2 and 2.3.

This work will allow us to define in the third part, the basis for future quality 4.0, which will rely on technologies 4.0 to multiply the benefits of Enterprise 4.0.

2.1. Quality versus Technologies 4.0

Table 1 corresponds to the strategic level of the overall company (For what? For whom?). Table 2 corresponds to the organisational level of the company within the processes or project vision (How?). Table 3 corresponds to the operational level of the company, including the workstations and activities (What?).

At each level of the organisation, there are examples of the mutual benefits between quality activities/tools and 4.0 technologies.

For example, at the strategic level (Table 1), digital twins are increasingly used to virtually model machines, equipment, plants, supply chains, products and customers. The generated model can be used to test various scenarios and identify opportunities for improvement at the highest level ([17], [18]).

On the other hand, it is important to check the quality of the data entering the digital twins to ensure the reliability of the results. The quality staff will be a key player in ensuring this reliability.

At the organizational level (Table 2), the Six Sigma method is a methodology used to improve the quality of products or services and reduce defects or errors. The goal of Six Sigma is to reduce variability and eliminate defects in processes, ultimately leading to increased customer satisfaction, improved productivity, and reduced costs.

It uses an approach based on statistical analysis and the search for the root cause of problems. The term "six sigma" refers to a level of quality that corresponds to only 3.4 defects per million opportunities.

The Enterprise 4.0 uses information and communication technologies (ICT) in an innovative and integrated way to improve the efficiency, quality and flexibility of the company.

The six Sigma method can also be useful in an Enterprise 4.0, because it can help identify and solve quality problems that can be caused by the integration of new technologies in the company's processes.

At the operational level (Table 3), sensors on

machines and products will make it possible to collect a large amount of data that can then be useful to the quality system. With processing and analysis technologies (big data analytics) [19], this data will make it possible to carry out the traceability and recording operations that are mandatory from a quality point of view. Potential problems can also be detected and resolved more quickly.

The data will also allow the identification of consumer habits and preferences for continuous improvement of products and processes. The quality system in response will manage all this data in a

relevant way. The list of quality tools and activities presented in this section is not exhaustive. However, when analysing these tables, it becomes clear that there is a very large number of quality tools/methods to implement the different quality activities. This large number contributes to the negative and restrictive "mille-feuille cake" perception of quality in companies. This is why we propose in section 3.2 a tool based on AI to limit the use of too many various tools. Companies are looking for this simplification.

Table 1: Quality and Technologies 4.0 at strategic level

| Strategic level (Overall company-Supply Chain) | |
|------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| For what? For whom? | |
| Quality activities (Define, Measure, Analyse, Improve/innovate, Control-DMAIC) | <i>Political:</i> What quality policy in relation to the company's objectives? What objectives/indicators? What risks/opportunities? What product quality characteristics? Improvements? <i>Economic:</i> Which stakeholders? Which markets? Financial resources? <i>Social:</i> What training for staff? What skills? Knowledge management? Human resources? |
| <i>Classification by PESTEL criteria</i> | <i>Technological:</i> What technologies? Knowledge management, Material resources <i>Environmental:</i> Which environment? What is the scope? Sustainable aspect, Material resources <i>Legal:</i> Which regulations? Which laws? Security aspect, GDPR aspect (General Data Protection Regulation) |
| Tools/Methods | <i>Management/quality tools/methods:</i> SWOT Analysis, PESTEL Analysis, Materiality analysis, SMART Objectives, Kaizen, Kaizen Quality Steering Groups, Plan-Do-Check-Act cycle [30], TQM, KANO Model, ISO 9001 (Quality Policy, Management Reviews, Quality Manual...), Quality Awards <i>Quality tools:</i> QFD matrix, COQ |
| Technologies 4.0 | Artificial intelligence, Simulation, Digital Twins Big Data, Cloud Computing, Cybersecurity Virtual reality I.e. Technology enabling anticipation (asynchronous). |

2.2. Difficulties for enterprises 4.0

The introduction of new technologies brings many benefits for companies, but also new challenges. The technical and human problems frequently cited by companies are:

- a) Data security: with digitalisation, companies have become more vulnerable to cyber-attacks, data breaches, and ransomware. Companies need to take appropriate security measures to protect the sensitive information of their customers and staff. [20].
- b) Data quality: data quality and relevance are fundamental (redundancy, double entry, control

to be organised also thanks to digital): the right data, at the right time and in the right place! Data storage and reliability must be managed both inside and outside the company ...for example in datacentres. [21].

- c) Human aspects (training - resistance to change - psychological issues): new technologies often require new technical skills and knowledge. [22].
- d) Technology introduction issues (obsolescence, interoperability, technology complexity, "techwashing"): with the speed at which technologies evolve, companies can quickly be faced with obsolete systems that are no longer

compatible with the latest standards and regulations. At the same time, companies also need to anticipate the increasing complexity and interoperability of technologies to remain competitive. [23].

- e) Technology dependency: companies can become overly dependent on new technologies, which can make them vulnerable to breakdowns, service interruptions or system failures. The use of systems that are only controlled externally (IT service providers, etc.)

is risky. It is therefore important for companies to have business continuity plans in order to minimise disruption in the case of technological failure. [23].

Companies need to be aware of these difficulties and take appropriate corrective actions to overcome them in order to maximise the benefits that new technologies can offer. The quality department can be a good support to help overcome these problems.

Table 2: Quality and Technologies 4.0 at organisational level

| Organizational level (Processes of Management, Operational, support and projects) | |
|------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| How? | |
| Quality activities (DMAIC) | <i>At processes level, Define, Measure, Analyse, Improve, Control:</i> Point of control, risks/opportunities, resources (Financial, Material, Human...), treatment of non-conformities, improvement actions, documented information, indicators, quality monitoring of processes, traceability, and external service provider assessments. |
| Tools/Methods | <i>Quality management methods:</i> PDCA cycle, BPR, Benchmarking, ISO 9001 (internal audits, process reviews, documented information (procedures, etc.), external service provider assessments), value analysis, quality meetings (top 30), cross-functional improvement groups <i>Tools/methods :</i> PQR Technique (Problem-Question-Resolution- 8D-A3 report) and tools (brainstorming, Cause-effect diagram...), 5S method, 6 sigma, Control charts, SPC, Quality plan, Risk analysis (ISO 31000 [24]), FMEA |
| Technologies 4.0 | Artificial Intelligence, Simulation, Digital Twins, Cloud Computing, Cybersecurity Augmented/virtual reality |

Table 3: Quality and Technologies 4.0 at operational level

| Operational level Activities (but not only production) | |
|---------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| What? | |
| Quality activities (DMAIC) | <i>At operational level, Define, Measure, Analyse, Improve, Control :</i> staff training, data storage, management of maintenance operations, adjustment, cleaning management, improvement actions, quality monitoring of production activities, indicators, problem resolution, treatment of non-conformities. |
| Tools/Methods | <i>Quality management concepts/methods:</i> PDCA cycle, ISO 9001, Quality Point (top 5), Quality Circles <i>Quality tools:</i> Poka Yoke, self-checking, QRQC and tools, traceability, non-conformity records, workstation instructions |
| Technologies 4.0 | Artificial Intelligence, GPT chat tool (quality document simplification) Cybersecurity Drones, Robots/collaborative robots, IoT- i.e. Cyber-physical systems, Augmented reality Internet of energy, Additive manufacturing, Radio frequency identification (RFID) i.e. Synchronous technologies |

2.3. Difficulties of quality departments and quality managers

Quality problems can affect any company, regardless of its size or sector.

To avoid these problems, companies must ensure that they comply with applicable standards and regulations, design quality products, use compliant materials and well-maintained equipment, select the best suppliers, listen to customer feedback, analyse business risks and opportunities, and establish a quality management system based on the implementation of robust and efficient processes.

W. Edwards Deming, the famous Quality Guru, said, "Quality is everyone's responsibility". In the real world, those in charge of quality encounter recurrent problems of resistance to change, poor image (stereotypes of quality managers/cops) and lack of involvement of management and staff. Staff complain about inefficient working groups (poorly defined objectives and problems), overwork, paperwork caused by the forced formalisation of know-how, time wasted on applying procedures and constraints, too many indicators to follow, and time-consuming reporting.

The technologies 4.0 can be an effective aid in solving problems, collecting and analysing data, reporting, follow the indicators and monitoring processes. [25].

3. QUALITY IN ENTERPRISE 4.0

As mentioned earlier, Enterprise 4.0 is characterised by extreme agility, modularity and speed. The life cycle of the quality system will also decrease. The modularity of time will also have to be taken into account. Notwithstanding this context of impermanence, the quality function must still be able to guarantee the satisfaction of all requirements. It is important to keep control of the processes even if the processes are largely automated and "smarter". What changes have these technologies brought about in quality? What changes in the quality manager's tasks? The following three sections will provide some pointers for reflection.

3.1. Towards Quality 4.0

The term "Quality 4.0" was introduced in 2015 in the report on the future of quality published by the American Society for Quality (ASQ) ([26], [27], [28], [29]).

To address the previously mentioned issues and changes related to Enterprise 4.0, our vision is that Quality 4.0 will have to be global, agile, pragmatic, and participative.

Quality must facilitate the rapid and optimal articulation between quality requirements and the introduction of new technologies at the level of products (operational level extended inside and outside the company), processes (organisational level) and the global system (strategic level). Quality must therefore be *global* because it acts both horizontally (suppliers, external service providers, customers, interested parties) and vertically (relations with all the company's departments and top management).

Agile quality is an approach that would aim to integrate the principles of agility into the quality management processes. This approach involves close collaboration between development teams, quality staff and customers. The aim is to respond rapidly to customer needs by adapting quickly to necessary changes.

Quality 4.0 is *pragmatic* because it uses new technologies to collect data in real time, monitor processes and detect anomalies. This approach allows companies to detect quality-related problems more quickly, make better decisions and improve product quality and customer satisfaction.

Quality 4.0 is *participative* because it focuses on the involvement of staff, customers and wider stakeholders. For example, employees are involved in identifying quality problems, taking corrective action and setting up prevention systems to avoid potential quality problems.

3.2. Towards a Quality AI

Artificial intelligence (AI) refers to a set of algorithms and techniques that aim to simulate human intelligence.

Machine Learning (ML) is one of the main AI techniques used today. Machine Learning algorithms autonomously learn to perform a task or make predictions from data and improve their performance gradually over time.

Table 4 proposes the first components of an AI decomposed into three levels corresponding to the three strategic, organisational and operational levels previously described. Thus, for each level, we could imagine an AI allowing helping the quality manager in his quality activities by using the incoming elements and generating the mentioned outputs.

For example, at the strategic level, an AI such as "Legal AI" should allow the quality manager to quickly identify the regulations and laws applicable to the country, the products (e.g. aeronautics, agri-food) and the systems concerned (e.g. nuclear).

Indeed, in the United States, Ross, the AI developed by IBM was developed to help professionals in professions requiring a detailed

knowledge and analysis of laws. [30].

The tool will also enable to propose the relevant "smart" objectives corresponding to the top management's quality policy as well as the quality characteristics of the products satisfying all the company's constraints.

Table 4: Focus on AI

| | |
|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Strategic level (Overall company-Supply Chain)</p> <p><i>For what? For whom?</i></p> | <p>Inputs :</p> <ul style="list-style-type: none"> Needs and expectations of relevant stakeholders Competitive context, sector, SWOT/PESTEL, regulations Customer needs and expectations Target products (market trend, innovation) Product information consumer feedback <p>Outputs :</p> <ul style="list-style-type: none"> Smart objectives according to the top management's quality policy Quality characteristics according to target products, risks/opportunities, supplier requirements, customer and legal requirements. Regulations and laws applicable to the country, the products and the systems concerned. |
| And reasoning/data used | |
| <p>Organizational level (Processes of Management, Operational, support and projects)</p> <p><i>How?</i></p> | <p>Inputs :</p> <ul style="list-style-type: none"> Products and customer requirements, regulations (sector, products, countries) - technical data <p>Outputs:</p> <ul style="list-style-type: none"> Quality system (processes, controls, indicators, documented information, risks/opportunities, supplier requirements, traceability, human resources) relevant to requirements. Quality plan for products |
| And reasoning/data used | |
| <p>Operational level Activities (but not only production)</p> <p><i>What?</i></p> | <p>Inputs :</p> <ul style="list-style-type: none"> Data collected at operational level via cyber-physical system Problems encountered (human, material, environment, methods, non-conforming products) - external data SMART objectives targeted <p>Outputs :</p> <ul style="list-style-type: none"> Quality monitoring List of corrective/preventive actions and indicators to verify. Associated risks and opportunities |
| And reasoning/data used | |

At the organisational level, the Quality AI will allow to quickly propose a quality system composed of processes, indicators, documents, human resources, supplier requirements, traceability requirements, risks and opportunities to be addressed...

For the operational level, AI will help to ensure rapid decision-making on basic quality elements (problems, controls, indicators, suppliers, etc.) for rapid control of the modular activities of the 4.0 company.

Of course, these three levels are necessarily interconnected and interdependent in the following ways:

- Top-down : e.g. quality policy and requirements will have an impact on the quality processes and activities of the lower levels, which will allow better coherence between the strategic vision and the operational implementation and

- Bottom-up: data measured and collected at the operational level will need to be analysed for reporting activities at higher levels.

3.3. New missions of the quality manager 4.0

In an Enterprise 4.0, the quality manager will be the pilot of the quality 4.0 defined in section 3-1. In addition to the historical tasks following the PDCA cycle [31] of planning, implementation of the process approach, quality monitoring, problem solving, continuous improvement and overall management of the quality system in all departments of the 4.0 company, new tasks will be added as part of the transition to Industry 4.0:

- a) The quality manager must be able to understand the new technologies and their technical and human impacts on the processes from a quality point of view. He/she must be able to manage the digital transformation of quality.
- b) The quality manager must be able to implement and use new technologies to monitor product quality, detect problems early, prevent potential problems, improve processes and reduce quality costs.
- c) Faced with the resistance and various human problems (resistance, psychology) raised by the introduction of new technologies, the quality manager will have to facilitate the transition through training, sensitisation, mentoring, etc.

In the particular case of the implementation of an AI (as suggested in the previous part), the quality manager 4.0 will be required to assist the computer

scientists and data scientists in the implementation and operation of this AI. He will probably participate in:

1. The construction (preparation and organisation of the data) of the starting base
2. The choice of the trained model
3. The learning, development and testing phases of the Quality AI
4. The organisation of the collection and control of the incoming data
5. Controlling the output results
6. Analysing feedback on the relevance of the proposed outputs (to further enhance the system) and improve the reasoning.

The capabilities and speed of an AI are largely impacted by the quality of the data injected and the way the input data is organised. The quantity of data can also increase the processing time of the AI. It is therefore important to control this data as much as possible. This is why phases 1, 4, 5 and 6 are important phases and the expertise of the Quality manager will be crucial.

4. DISCUSSION

Despite the progress made in recent years in artificial intelligence and the years of field experience in quality management, there are still possible improvements that require further research. The improvements mentioned in this part concern explainable AI and the necessary evolution of the ISO 9001 standard. The last paragraph concerns the main limitations of this research work.

4.1. An explainable AI for Quality 4.0

Explainable AI, also known as "XAI", is a branch of artificial intelligence that aims to ensure that the decisions made by machine learning models are understandable to humans. In contrast to many AI systems that operate as "black boxes", explainable AI systems allow us to understand how and why a decision was made. ([32], [33], [34])

This can help users understand the limitations and potential biases of algorithms, improve confidence in the results and facilitate decision-making by providing understanding of the reasoning behind them.

The use of explainable AI could provide the quality manager with valuable assistance in deciding, collecting, tracing data. This AI must be specific to each company according to its products, its customers and stakeholders, its sector of activity,

its context, and its own regulatory constraints.

Explainable AI is certainly the most relevant AI for the quality system of Enterprise 4.0 because it allows anyone, even non-technical specialists or data scientists, to understand how the models lead to a decision. Explainable AI promotes transparency and trust, both internally and externally, by providing better traceability of data in the quality domain. It thus enables results to be explained internally (management, staff in contact) and externally (customers, service providers, etc.) and reduces the risks of bias [34], errors (known as hallucinations) and complexity leading to excessively long reasoning times. This AI will simplify the day-to-day management of quality in companies and allow quality managers to focus on innovation rather than on the basics of quality.

4.2. Towards a new version of the ISO 9001 standard

Another Quality Guru, Philip Crosby said, "Good things only happen when planned, bad things happen on their own". Those "good things" that happen are not the result of chance, but rather the result of proper planning, implementation of an action plan, monitoring and possible adjustments or improvements to ensure that everything goes according to plan. This corresponds to the PDCA cycle. This quote therefore encourages planning and risk management to minimise unexpected problems and maximise the chances of success. The PDCA cycle and risk management are present in quality management system standards such as ISO 9001. It would therefore be appropriate to have a 'framework' based on the essentials of quality management standards (such as ISO 9001) but which allows the introduction and use of future enterprise technologies to be planned and controlled while ensuring that requirements are met. For example, Fundin et al. [35] argue that stability in change is an essential component of future Quality. For example, ISO 9001 should reduce the requirements for documented information, procedures, instructions and records, and internal audits on compliance of documentary aspects, which are less relevant due to the presence of 4.0 technologies. On the other hand, it must be more precise in order to improve the taking into account of (Note that the chapters mentioned below correspond to the chapter titles of the ISO 9001 standard):

- a) The "Data" aspect by integrating requirements for the accurate and secure management of data inside and outside the company in chapter 7.5 on documented information and chapter 7.1.3 on infrastructure. For example, the new version of ISO 27001 published in January 2023 specifies the important elements of a security and information management system [36].
- b) The extreme variability and modularity of the process approach in the case of variations in product requirements (Chapter 4.4 dealing with Quality management system and its processes).
- c) The equipment management aspect (Chapter 7.1.3 dealing with Infrastructure).
- d) Competence management (Chapter 7.1.2 dealing with People).
- e) Knowledge management (Chapter 7.1.6 dealing with Organizational knowledge).
- f) Management of external service providers (Chapter 8.4 dealing with Control of externally provided processes, products and services).
- g) The dashboard evolution of indicators varying according to the products and processes. (Chapter 4.4 dealing with Quality management system and its processes).
- h) Data from the product (Chapter 9.1 dealing with Monitoring, measurement, analysis and evaluation).
- i) Energy aspect (Chapter 7.1.4 dealing with Environment for the operation of processes).

The use of quality standards will be particularly important in safety-critical sectors such as the nuclear sector (ISO 19443: 2022) [37], the food sector (ISO 22000: 2018) [38], the aerospace sector (EN 9100: 2018) [39], and the medical sector (ISO 13485: 2016) [40].

4.3. Limits of the research

The research work presented here is an exploratory work that allows, firstly, establishing an overview of quality at the three strategic, tactical and operational levels of the enterprise 4.0 (Tables 1-2 and 3). The objective of this analysis is to highlight the beneficial interactions between the new technologies and the company's quality activities. Examples of win-win links between new technologies and quality tools are explained in section 2.1. It would be necessary to complete and detail this study to truly establish the necessary articulation between new technologies and quality activities.

Then, paragraph 3 focuses more specifically in the interest of AI to help quality management at all levels of the company (Table 4). Developing AI systems for industrial quality control requires a deep understanding of the manufacturing process, as well as expertise in AI. It also requires close collaboration between researchers, engineers, and quality experts to ensure that the AI system meets the specific needs of the industrial setting. It would therefore be necessary to deal with a real industrial case to complete and validate the first defined elements of the AI proposed in paragraph 3.2.

Finally, we have to be aware that one of the main difficulties will be that an AI for quality management requires a large volume of data to train the algorithms. The data must cover all possible scenarios, including rare and unusual cases. Moreover, ensuring the accuracy and reliability of the data is essential to avoid biases in the model. Ensuring that the AI system is compliant with regulatory requirements is also essential in industries such as healthcare or aeronautics. Developing AI systems that comply with regulatory requirements can be challenging, as the regulations are complex and vary across various sectors and countries.

5. CONCLUSIONS

The aim of introducing new technologies into companies is to enable them to be intelligent, agile and flexible, so that they can adapt quickly to changes in the market and respond to customer needs.

In this context, quality management remains essential to ensure the improvement of the enterprise 4.0.

As the traditional approach to quality is no longer fully adequate, the concept of quality 4.0 has emerged. It is a modern approach to quality management that takes advantage of new technologies and data to ensure that customer, regulatory and legal requirements are satisfied, while improving efficiency, flexibility and overall quality performance.

The role of the quality manager is therefore to drive quality 4.0 and to act as an arbiter in decisions related to quality and new technologies. The use of a quality-specific explainable AI would help in decision making at strategic, organisational and operational levels.

This work has opened the way for a new axis of

research on the articulation of quality in a context of transition to Enterprise 4.0, with foundations for Quality 4.0 and quality-specific explainable AI.

Future work may include the development of a detailed specification for Quality AI based on a real company case.

This approach could also be extended to integrated Quality Safety and Environmental (QSE) systems to assist safety and environmental managers in a context of resource constraints (scarce raw materials and energy) and increased regulation.

Table 5: Tools and Techniques

| Tool/technique | Short definition |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5S method | Technique for organizing and standardizing the workplace that follows five principles: sort, put in order, shine, standardize and maintain. |
| 8D-A3 report-QRQC-DMAIC | Structured, team-based problem-solving methodologies. (8 Disciplines, Quick Response Quality Control, Define-Measure-Analyse-Improve/innovate-Control) |
| Benchmarking | Process of comparing an organization's products, services, or processes against industry best practices or competitors' performance. |
| Control charts | Statistical tools used in quality control and process improvement to monitor, analyze, and visualize process variations over time. |
| COQ | Cost of Quality is a financial indicator that quantifies the costs associated with preventing, detecting, and correcting defects in products or services. |
| FMEA | Failure Modes and Effects Analysis' is a systematic, proactive approach for identifying potential failure modes in a product or process. |
| Kaizen | Continuous improvement philosophy that focuses on small, incremental changes in processes. |
| KANO Model | Product development and customer satisfaction framework that classifies customer preferences into distinct categories. |
| Materiality analysis | Materiality analysis is a process to identify, assess and prioritize the most relevant issues for an organization and its stakeholders. |
| PDCA Cycle | Continuous improvement model that involves planning a change, implementing it, evaluating its effectiveness, and then making adjustments as needed. (Plan-Do-Check-Act) |
| PESTEL analysis | Framework used to assess the external macro-environmental factors (Political, Economic, Sociocultural, Technological, Environmental, and Legal). |
| Poka Yoke | Technique that aims to prevent errors and defects from occurring in products or services. |
| QFD matrix | The Quality Function Deployment matrix is a structured approach that translates customer requirements into design, process, and quality characteristics. |
| Quality awards | Prestigious recognitions that demonstrate excellence in quality management systems and processes. (Deming, Malcolm Baldrige, EFQM (European Foundation for Quality Management)) |
| Reengineering | Organizational transformation approach that involves fundamentally rethinking and redesigning business processes. |
| SMART matrix | Tool for setting objectives that are Specific, Measurable, Achievable, Relevant, and Time-bound. |
| SPC technique | Statistical Process Control is a quality control technique that utilizes statistical methods to monitor, analyze, and control process variation. (Cp and CpK), |
| SWOT analysis | Strategic planning tool that evaluates an organization's internal strengths and weaknesses as well as external opportunities and threats. |
| TQM | Holistic management approach that seeks to continuously improve organizational processes, products, and services. (Total Quality Management) |

ACKNOWLEDGEMENT

The authors thank David Janiszek (University of Paris Cité) and Frédéric Pereyrol (University of Bordeaux) for their scientific contributions.

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