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Promote Competency-Based Training Approach in Quality, Regulatory and Clinical Affairs to Improve MD/IVDD Safety and Performance

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Abstract: The aim of this paper is to analyze the training needs introduced by the implementation of the European regulations on medical devices (MDR) and in vitro diagnostic medical devices (IVDR), and to analyze the appropriateness of a competency-based training approach. Finally, a number of ideas are put forward concerning certain topics to be addressed in a Europe-wide approach.


1 INTRODUCTION


The European regulations on medical devices MDR (EU) 2017/745 applicable since 26/05/2021 and (EU) IVDR 2017/746 on in vitro medical devices applicable (IVDR) since 26/05/2022, define and reinforce the role and tasks of the person responsible for ensuring compliance with the regulations, particularly within manufacturers and notified bodies.

However, this is not a new activity for medical device manufacturers. Since the introduction of CE marking for medical devices (MD) then in vitro medical devices (IVDD), since 1990, these activities have tended to be entrusted to engineers in the R&D

departments, then to those also in charge of the company's 'quality' activities, more often as an additional related activity to the technical day-to-day work, depending on the size and organization of the companies. In fact Regulatory Affairs, Quality and Clinical Research are much linked activities in a company and ultimately transversal.

Nevertheless, the current EU regulation formalizes these roles with certain jobs profile to guarantee the safety and performance of medical devices, both within economic operators (manufacturers, authorized representatives, distributors and importers) and in notified bodies (which are private companies). For the latter, the staff

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qualification criteria that all notified bodies must meet are specified in Annex VII - part 3, and in particular in paragraphs 3.2.4 and 3.2.5.

The current EU regulation strengthens its requirements, particularly in the area of clinical evaluation and the provision of clinical evidence, for which manufacturers and notified bodies do not seem to be sufficiently prepared.

It is therefore legitimate to ask what training courses the medical device industry could turn to at the European level in order to meet the current requirements of the MDR/IVDR and its concrete implications in terms of the skills to be acquired and maintained.

2 ANALYSIS OF NEEDS, BUSINESS PROFILES TO BE TRAINED

Internationally, Regulatory Affairs Professionals Society (RAPS) has initiated a number of recent actions in the field of medical device regulation, with many differences in approach from one country to another.

In US, FDA (Food and Drug Administration) provides and updates a dedicated page about regulatory sciences (<http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/default.htm>), and has developed in that sense several actions and programmes for years.

France's leading trade association in the field, SNITEM, has carried out surveys among its members to identify the profiles needed to be recruited, and has begun to draw up job descriptions for Regulatory Affairs and Quality, including one for the Regulatory Affairs Manager in the medical device industry (SNITEM 2020). Usually reporting to General Management or the Quality Department, this person is responsible of regulatory compliance according to the MDR/IVDR. Furthermore, he/she defines and deploys the company's technical and regulatory strategy from development, registration and operation through to the end of the medical device's life. This job profile needs to be strengthened and revised, in particular through ongoing training, if we are to meet the current clinical evaluation requirements expected under the current European regulations. The skills required are becoming so diverse and specialized that there is an urgent need to think about the different professions to be initiated, as a single person can no longer satisfy all the requirements.

Again in France, the national working group led in 2019 by the Ministry of Higher Education, Research and Innovation with numerous stakeholders (SNITEM, Pharmacy Deans Conference, French's biomedical engineering schools., EUROPHARMAT, Tech4Health network, INSERM F-CRIN clinical research infrastructure, French Pharmaceutical Students' Association, and the GMED notified body), wanted to compare this regulatory activity, in terms of its missions, with the responsible pharmacist in the pharmaceutical industry. The EU MDR and IVDR (article 15) introduce the role of the person responsible for regulatory compliance (PRRC). Some uncertainties remain as to the implementation of this role. PRRCs must demonstrate that they are suitably qualified for the role. The fact that it was not compulsory before 2021 and the absence of official job descriptions for medical devices have so far limited the creation of a structured academic training program spread evenly across the country. The situation seems similar in many European countries.

For a company, the absence of a suitable job profile to meet the current requirements of the European regulation on medical devices in a CE marking application file could de facto lead to the risk of failure of the certification process of the corresponding medical devices submitted to the notified bodies. This risk is low for large companies in the sector, but high for Small and medium-sized enterprises (SMEs). Yet, SMEs account for more than 90% of European medical device companies. These companies rarely have someone in their organizational chart who is solely responsible for regulatory affairs and has specific training as required by the current European regulation. This finding also indicates that, in addition to specific skills, we need to consider a larger number of people to train. Furthermore, when they set up their start-ups, the entrepreneurs themselves are often unprepared for the regulatory procedures required to get their products to the market. This often results in serious and impactful delays and/or failures within the first three years.

First and foremost, therefore, action needs to be taken in the field of continuing training to bring active professionals up to date with updated and enhanced diplomas or certifications in QMS, regulatory and clinical affairs, and, at the same time, to train the professionals of tomorrow to 'arm' new companies or those that do not yet have such qualified resources in-house. In addition, continuous training cycles should be envisaged, short, compatible with the daily workload, and progressive, designed to keep professionals up to date with the latest regulations.

It should be noted that these training courses are not solely aimed at manufacturers of devices, but also and non-exclusively at those who distribute and assess them, as well as consultants, notified bodies, the competent authorities, etc.

For example, in France, which accounts for just over 10% of European medical device companies, the national working group led by the Ministry of Higher Education, Research and Innovation mentioned above, estimates there is a need to train 1,000 people in regulatory affairs and quality over the next 5 years. On this basis, a rough assessment of the need in Europe could be envisaged with a factor of ten.

3 THE SKILLS-BASED APPROACH TO TEACHING

The skills-based or competency-based approach to pedagogy has evolved over the decades, reflecting changes in educational needs, perspectives on learning, and theoretical developments in the field of education.

3.1 History

The first work on the competency-based approach appears to have emerged in the 1960s, notably with the work of the American psychologist David McClelland (in Bouteiller 2016). He introduced the concept of behavioral competencies, focusing on the individual attributes and abilities needed to succeed in specific situations. The development of competencies was subsequently taken further, with researchers such as Richard Boyatzis and others developing more specific competency models, distinguishing technical competencies from social and emotional competencies. Competencies, in this line of research, were defined as "underlying characteristics of the person that led to or caused effective or superior performance" (Boyatzis, 1982). The competency-based approach was gradually introduced into the field of education in the 1980s and 1990s. Education reforms in some countries, such as France, have incorporated this approach to better align education with the needs of the labor market. Educational reforms around the world have often incorporated elements of the competency-based approach. The emphasis has been on developing cross-disciplinary skills such as critical thinking, creativity, communication and collaboration. The 2000s saw a proliferation of competency frameworks, describing the competencies expected at different

levels of education. These reference frameworks have often been developed in collaboration with the professional world to ensure direct relevance.

3.2 The Competency-Based Approach in University Education

The competency-based approach to university education in engineering and health has been adopted by a number of countries around the world, with the aim of better preparing students for the practical challenges of their future careers. The competency-based approach has been gradually integrated into engineering training in France since 2000. The "Grandes Écoles d'ingénieurs" were pioneers in this development. In the healthcare sector, the introduction of competencies in medical training was initiated with the reform of medical studies in 2009. The aim of this approach is to train professionals capable of meeting the real needs of the healthcare system. Since 2022, the Objective Structured Clinical Examination (OSCE) has been a new national assessment method for French medical students at the end of their second cycle of medical studies, with a view to awarding them their internship. This simulation-based tool provides a standardized assessment of professional behavior and performance, and everything that Multiple Choice Type Questions (MCQs) cannot assess: reasoning, behavior, communication, professionalism, etc. OSCE was first developed in Canada and then in Switzerland.

In Canada, universities have been gradually adopting the competency-based approach in engineering programs since the 2000s. The emphasis is on developing practical skills and preparing students for the professional environment. Health programs, particularly in medicine and nursing, have integrated the competency-based approach for many years to align training with the needs of the health system. This includes clinical placements and practical assessments based on simulated or real-life situations.

Australian universities have begun to adopt the competency-based approach in engineering programs over the last few decades. The aim is to produce engineers who are adapted to the requirements of industry. Health programs in Australia, such as medical education, incorporate the competency-based approach to prepare students for various aspects of medical practice, including communication, inter-professional collaboration and clinical skills.

In the Netherlands, the competency-based approach has been increasingly integrated into engineering programs since the 2000s, with an emphasis on practical and professional skills. Health training programs in the Netherlands have adopted the competency-based approach to train multi-skilled health professionals capable of adapting to rapid changes in medical practice, particularly in the context of digital health.

The arguments in favor of the skills-based approach in these countries include the need to better align training with the real current and future needs of the labor market, to encourage the development of practical and professional skills, and to prepare students to be operational as soon as they enter the professional world. This approach also aims at fostering students' autonomy, creativity and ability to adapt to various situations they will encounter in their future careers, and so particularly suitable to the complexity of medical device field and the projects that could be said to be almost each tailor-made.

3.3 Recent Developments

With the advent of information technology, the skills-based approach has broadened to include digital skills. Modern societies now require individuals to master technology-related tools and skills. The rapid evolution of society has led to the recognition of 21st century skills, encompassing critical thinking, problem solving, creativity, collaboration, communication, digital citizenship, and lifelong learning.

Although the competency-based approach has developed significantly, it also faces challenges and criticism. Some question the standardization of skills, stressing the importance of contextual and cultural skills. In addition, assessing skills remains a complex challenge.

4 COMPETENCY-BASED APPROACH TO MDR/IVDR TRAINING

A competency-based approach to training in European regulations on medical devices would be of major interest in the current context of companies that are often small in size, and having a business based on small specialized product ranges. This approach, which focuses on developing the practical skills of professionals, offers a number of significant advantages.

4.1 A Specific Area

It is important to stress that European regulations on medical devices are a complex and constantly evolving field. Professionals working in this sector must not only understand the regulatory texts, but also be able to apply them concretely in their daily practice, anticipating the constraints imposed. For example, it would be totally counterproductive to choose materials for the components of a medical device in contact with biological tissues solely on the basis of their physico-chemical or mechanical properties, if these materials turned out not to be biocompatible. The skills-based approach makes it possible to meet this requirement by emphasizing the acquisition of specific know-how and the ability to solve concrete problems related to regulations.

4.2 Specific Skills

By adopting this approach, training courses can focus on developing key skills such as interpreting standards, quality and risk management, regulatory monitoring and implementing good clinical practices (GCPs). In this way, graduates would be better prepared to meet the practical challenges they will face in their professional environment. The aim is to go beyond the simple acquisition of theoretical knowledge to foster a genuine range of the skills needed to assume responsibility for regulatory compliance.

In addition, the skills-based approach encourages the development of critical thinking and adaptability. In the field of medical devices, regulations can evolve in response to technological advances, safety issues, feedback from experience and use, or updates in clinical practices or “gold standards” Professionals trained in this approach will be better prepared to assimilate new information, adjust their practices and innovate in compliance with current regulatory standards.

This approach also encourages cross-disciplinary skills. Professionals in the medical devices sector often have to work with experts from different disciplines (engineers, clinicians, quality managers, etc.) both inside and outside the company. Competency-based training helps to develop a global and interdisciplinary understanding of regulations, strengthening the ability of teams to work coherently and collaboratively.

Finally, the skills-based approach means that the realities of the field are better taken into account. Professionals are faced with a wide variety of situations, some of which are unforeseen.

Competency-based training prepares them to manage these situations by mobilizing the knowledge they have acquired through their experience and training in a relevant and effective way. This helps to ensure that regulations are applied more effectively and that the quality and safety of medical devices on the European market are optimized.

4.3 Integrating Clinical Evaluation into MDR/IVDR Training Courses

The integration of clinical evaluation into training courses devoted to European regulations on medical devices has become a strategic obligation in order to train competent and well-prepared professionals in this specific field. Clinical evaluation brings a practical and concrete dimension to the understanding of regulatory requirements, offering several significant advantages.

It is essential to emphasize that European regulations on medical devices attach particular importance to clinical evaluation, which is considered to be a central element in demonstrating the safety and performance of medical devices. The inclusion of this dimension in training enables professionals to fully understand the challenges and usefulness of their work, and underlines the importance and scope of clinical evaluation in the process of bringing medical devices to market.

Clinical evaluation in training courses offers a unique opportunity to apply the theoretical knowledge acquired through documentary research or e-learning to practical situations. Learners are confronted with real-life cases that simulate the challenges they will face in their professional practice. This not only reinforces their understanding of regulatory concepts, but also enables them to develop specific skills related to planning, conducting and analyzing relevant and demonstrative clinical evaluations, in relation with the specialists in the medical and clinical research field. It is also to notice that MDR underline the importance for manufacturers (but also notified bodies) to be surrounded and use support by clinicians' experts when necessary.

By integrating clinical evaluation into their training, professionals acquire an in-depth understanding of the methodologies and good practices associated with this process. This includes designing evaluation protocols, thinking about how to collect and analyze clinical data, managing clinical risks, and communicating results to patients, healthcare professionals and the relevant authorities. These practical skills are essential to guarantee

compliance with regulatory requirements and ensure patient safety.

Clinical evaluation also encourages professionals to develop a critical and ethical approach. They are required to critically appraise clinical evidence (in particular to establish the state of the art, the first pillar of any clinical evaluation), to anticipate and resolve potential ethical problems, and to ensure informed decision-making based on the results of the evaluation. These skills are crucial in a regulatory environment where patient protection and the quality of clinical data are absolute imperatives.

The inclusion of clinical evaluation in training courses also strengthens interdisciplinary collaboration. Professionals working in the field of medical devices often have to collaborate with clinicians, researchers, statisticians and other experts. Training that includes clinical evaluation encourages teamwork, effective communication between the various stakeholders and an understanding of the issues specific to each discipline.

4.4 Ways of Developing a Skills-Based Approach to the MDR/IVDR

The skills to be acquired should initially be defined in **terms of knowledge, know-how and interpersonal skills for each of the job profiles envisaged at the end of the course** (e.g. *Regulatory & Clinical Affairs Manager, Clinical Affairs Project Manager, Regulatory Affairs Project Manager, Notified Bodies –NB Auditor, NB Internal Clinician, NB Clinician specialist, Competent Authority Project Manager, Hospital MD quality management system manager...*).

It should be possible to define a level of expertise according to the profile envisaged, to be reached at the end of the training:

- ✓ Basic: basic skills = the person has been given the concepts, knows how to find the resources to do what they need to do, given time and a guide (written document, tutorial or coach).
- ✓ Acquired: competence acquired = the person knows how to manage standard cases autonomously. If there are no particular difficulties, they can manage on their own but need help with difficult cases.
- ✓ Expert: fully mastered skill = the person knows how to do standard cases very well, but also difficult or complicated cases independently. This person could manage and train other people to improve control of the activity.

By way of illustration, here are a few new skills in the field of clinical evaluation that could be envisaged for a person responsible for Regulatory & Clinical Affairs:

- ✓ master the relevant requirements of the regulation, common specifications, guidance documents and harmonized standards,
- ✓ be able to carry out a clinical evaluation with its various components and in collaboration with an expert team (state of the art, clinical investigation, opinion of clinical experts, equivalence analysis)
- ✓ be able to issue a reasoned judgement on the opinion given by any external clinical expert and extract a scientific and ethical summary from these expert opinions,
- ✓ be able to write synthesize this information and based on that provide decisions, by reports demonstrating that the clinical evaluation activities (for CE marking or its renewal) have been carried out adequately.
- ✓ Be able to analyse the risks associated with the use of medical devices
- ✓ Be able to take part in strategic regulatory analysis for the development of a new type of medical devices
- ✓ Be able to use adequately new tools based on Artificial Intelligence as ChatGPT or Elicit.

More generally, on completion of the course, graduates intended for companies should be able to contribute actively, with a high level of autonomy, to the activity of the company's regulatory affairs department (management of CE marking applications). The training should enable them to support the regulatory activities of clinical trials, vigilance and post-market clinical follow up. Graduates will have a detailed knowledge of the requirements and organization of the healthcare industry, and should be able to work within it, with the necessary interaction between departments. They will also be able to understand, analyze and respond to requests from notified bodies and health authorities. Graduates will thus be destined to occupy a position of senior management responsibility immediately.

Students heading for the manufacturing industry will need among other things to be able to:

- interpret a medical need or regulatory issue arising from the professional environment,
- develop and implement a working methodology for the design of new medical

devices, in compliance with standards and regulations (including GDPR)

- Identify the issues at each stage of the medical device's life cycle, from the idea to post-market surveillance,
- evaluate and optimize the performance of new medical devices, particularly during their development, with an ecological perspective of sustainable development,
- contribute to and collaborate on an interdisciplinary project in the field of health technologies,
- understand the needs/expectations/constraints of all the players involved in order to facilitate market access for an innovation,
- communicate scientific results clearly, ethically and rigorously,
- etc.

The training program should include the learning of "soft-skills" such as:

- Project management: tools and methods
- Literature monitoring (scientific and regulatory)
- Communication skills: practicing oral and written presentations (poster, flyer, promotional literature, etc.)
- Skills in managing project meetings
- Crisis management (simulation model)
- Use of tools based on Artificial Intelligence

A number of teaching methods (e-learning, streaming, videoconferencing, webinars, reverse learning with interactive videoconferencing of questions, Masterclasses, mini-projects, cycles of meetings with entrepreneurs, observation periods in companies, work experience with experienced professionals in the same way as the ECOS mentioned above, etc.) should be available in addition to traditional work placements or alternating with work in a professional environment.

Each student should have a personalized course portfolio. Each planning is intended to be shared by the resource people involved in the learner's training pathway.

It should be used to monitor the student's progress through the program and to capitalize on the skills acquired during the course and work placement in order to obtain the University Diploma.

The main objectives of this tool are:

- encourage self-assessment of the gap between the knowledge acquired (courses received) and the know-how required

- (practical application during projects and placements);
- enable the referents and trainers involved to understand where the learner is in his or her vocational training pathway and to better measure the remaining needs;
- position what has been learnt in relation to what is required at the end of the diploma;
- Encourage self-motivation, as each student is involved. Indeed the choice of courses will depend on his/her own objectives, so he/she may feel even more involved with the training.

The acquisition of skills during training should be attested by a formative assessment mechanism throughout the course and finally by a summative assessment leading to certification or a university diploma.

5 TOWARDS A EUROPEAN APPROACH TO MDR/IVDR TRAINING

European regulation of MD/IVDD is a complex and crucial area that governs the marketing of these products in the European Union. Although the regulations themselves are harmonized at the European level, there may be variations in the approaches taken by different member states regarding training on these regulations. This comparison could highlight differences in teaching methods, priorities and resources invested in training professionals in the medical devices sector.

5.1 Differences to Be Aware of

It is important to note that variations between the approaches of different European countries may originate in cultural & political differences, national health priorities or distinct educational systems. Some countries may place greater emphasis on specific skills related to the regulation of MDs and IVDDs due to particular needs within their healthcare system.

Although the European regulations on MD and IVDD are the same for all European countries in terms of the equivalent of marketing authorization, there are other regulatory points to be taken into account by manufacturers wishing to establish themselves on the European market.

After CE marking, clinical studies on medical devices are usually carried out for two purposes:

- to convince physicians of the device's interest and clinical usefulness
- to enable decision-makers to determine the eligibility of these new devices for reimbursement.

Both objectives require in-depth knowledge of country-specific regulations, which are not covered by the RDM or IVDR:

- regulatory procedures for initiating clinical trials
- regulatory procedures for obtaining reimbursement.

In this section, we will focus solely on the procedures for obtaining reimbursement, identifying the organizations in the main European countries and the criteria for reimbursement eligibility.

The reimbursement mechanisms for medical devices vary from one European country to another, depending on their respective health systems and political choices. This point is not covered by RDM and RDIV. Reimbursement procedures are not managed at EU level, and each country's procedure should therefore be known by any company wishing its product to be distributed throughout Europe. CE marking certainly gives a license to place the product on the market, but, in most cases, the hardest part is still getting the market to adopt and buy the product. The reimbursement stage is therefore crucial, and is specific to each country. This information is vital not only for manufacturers, but also for all those involved in the development and evaluation of medical devices in Europe.

Here are a few examples from the main European countries.

In France, medical devices are reimbursed by the national health insurance "Assurance Maladie." The French National Authority for Health (HAS) assesses the relevance of medical devices before they are reimbursed. Devices are classified into categories (LPPR - Liste des Produits et Prestations Remboursables) according to their medical usefulness. This reimbursement system has been in place for several decades, but HAS assessments have been strengthened over time. France aims to ensure that patients have access to high-quality medical devices while controlling costs. Relevance assessments by the HAS aim to ensure the effectiveness and safety of the devices reimbursed.

In Germany, medical devices can be reimbursed by health insurance funds. The decision to reimburse depends on an assessment by the Federal Institute for Quality and Efficiency in Health Care (IQWiG), a process that was strengthened in the early 2000s.

Germany seeks to guarantee the efficiency of healthcare spending by rigorously evaluating the effectiveness of medical devices before they are reimbursed.

In the UK, medical devices are assessed by the National Institute for Health and Care Excellence (NICE). Since Brexit, UK no longer applies RDM and IVDR, but a specific attention is given to product already CE marked. Reimbursement is determined by Clinical Commissioning Groups (CCGs) within the National Health Service (NHS). NICE was set up in 1999, but the appraisal process has been strengthened over the years. The UK seeks to optimize the use of resources by assessing the clinical value of medical devices to ensure the best quality of care.

In the Netherlands, medical devices are assessed by the Dutch College of Health Technology Assessment (ZIN). Reimbursement is managed by compulsory health insurance. The current system has been in place since 2000. Patients have to pay from their own pockets in some cases. "The "own risk" amount ("eigen risico"), which is an annual amount that you must pay out of your own pocket for some treatments and medicines before your health insurance will cover the rest ». The Netherlands seeks to ensure the quality and effectiveness of healthcare by assessing medical devices before reimbursing them.

These approaches aim to reconcile patient access to innovative medical devices, cost containment for healthcare systems and quality assurance of care. Prior assessment aims to ensure that reimbursed medical devices are both clinically effective and economically viable.

In Belgium, medical devices are reimbursed by the INAMI (Institut national d'assurance maladie-invalidité). Reimbursement is based on a specific nomenclature, the List of Products and Services (LPP), which sets out the conditions for reimbursement for each medical device. The reimbursement system for medical devices has been in place for several decades, and adjustments have been made over time. Belgium's aim is to guarantee patient access to essential medical devices while maintaining rigorous management of healthcare expenditure. The nomenclature aims to standardize and control reimbursements to ensure that resources are used appropriately.

In Poland, reimbursement of medical devices is managed by the National Health Fund (NFZ - Narodowy Fundusz Zdrowia). Medical devices must be included on the list of reimbursable products to be eligible for reimbursement. The reimbursement system for medical devices in Poland has evolved

over the years, becoming more formally structured over the last two decades. Poland seeks to ensure fair access to medical devices by reimbursing those that meet the health needs of the population. Inclusion on the list of reimbursable products is based on criteria of effectiveness, safety and impact on public health.

In these last countries, reimbursement mechanisms aim to ensure equity of access to necessary medical devices while maintaining efficient management of healthcare system resources. The establishment of specific lists and the definition of eligibility criteria are approaches adopted to guarantee the clinical and economic relevance of reimbursed medical devices.

In Spain, reimbursement for medical devices is part of the Sistema Nacional de Salud (National Health System). Medical devices are included in the health system's common catalogue of services, and reimbursement is determined on the basis of criteria of effectiveness, safety and clinical usefulness. Access to medical devices is based on a doctor's prescription. The reimbursement system has been in place for several decades, with regular adjustments over time. Spain also aims to guarantee equitable access to necessary medical devices, ensuring that their use is based on sound clinical evidence. The system also aims to maintain the economic viability of the healthcare system.

In Portugal, reimbursement of medical devices is managed by the Serviço Nacional de Saúde (National Health Service). Medical devices are included in the Index Nacional de Dispositivos Médicos (INDM - National Index of Medical Devices), which determines the conditions for reimbursement. Access to devices is also linked to medical prescription. Portugal aims to guarantee the quality of healthcare by reimbursing medical devices that meet high standards of effectiveness and safety. Using the INDM facilitates the management of reimbursements and ensures transparency in the process.

In Italy, reimbursement of medical devices is managed by the Servizio Sanitario Nazionale (National Health Service). Medical devices are included in the Tariffario Nazionale delle Prestazioni (National Tariff of Benefits), which defines costs and reimbursement conditions. Access to devices is conditional on a doctor's prescription. Italy aims to guarantee effective healthcare by reimbursing medical devices that meet quality standards. The Tariffario Nazionale delle Prestazioni facilitates cost management while ensuring the availability of necessary devices for patients.

In these last three countries, coverage for medical devices is based on national healthcare

systems. Access to devices is generally linked to a medical prescription, and reimbursement arrangements are defined by national catalogues or tariffs. The arguments put forward are to guarantee access to the necessary medical devices while ensuring their clinical effectiveness and the economic viability of the healthcare system.

5.2 Differences in Teaching Methods to Be Explored

In terms of teaching methods, some countries may favor a more practical approach, focusing on concrete case studies and simulations, while others may opt for a more theoretical and academic approach. These differences may be influenced by national educational traditions and the resources available for training.

The levels of detail and requirement in training programs may also vary. Some countries may impose stricter standards and require more in-depth training, while others may adopt a more flexible approach, leaving healthcare professionals more room for maneuver in understanding and applying the regulations.

Furthermore, EU member countries may have different priorities when it comes to regulating medical devices, depending on their own public health challenges, the size of their medical device industry and their specific economic circumstances. For example, a country with a strong medical device industry may place greater emphasis on the training of industry professionals, while a country with an ageing population may pay particular attention to the training of healthcare professionals involved in the clinical use of medical devices.

The financial and human resources devoted to training can also vary considerably from one country to another. Some countries may invest more in the development of sophisticated training programs, while others may be resource-constrained and favor more cost-effective approaches.

Despite these differences, it is important to emphasize that the common objective of all training approaches in the EU is to ensure that professionals comply with common regulatory standards and that medical devices are safe for patients. Collaboration between regulators, training organizations and healthcare professionals can help to further harmonize these approaches and share best practice, and at the same time to personalize the way an expert that will be trained can provide the most adapted intervention and impact positively a medical device project.

6 CONCLUSION

In conclusion, a training strategy adapted to regulatory constraints can be a formidable tool in the service of EU competitiveness.

The competency-based approach to training in European regulations on medical devices represents a relevant teaching strategy that is adapted to the current challenges facing the healthcare industries. By focusing on the development of practical skills, this approach provides professionals with the tools they need to successfully navigate a complex and constantly changing regulatory environment.

More specifically, integrating clinical evaluation into training courses devoted to European regulations on medical devices offers substantial advantages. It enables professionals to acquire essential practical skills, to fully understand the importance of the issues at stake and of clinical usefulness, and to develop a critical and ethical approach. These skills are essential for ensuring regulatory compliance, patient safety and the quality of medical devices on the European market.

A comparison between the approaches of different European countries to training in European medical device regulation could reveal significant diversity in terms of teaching methods, national priorities and resources allocated. However, it would be essential to maintain a degree of fundamental harmonization to ensure the effectiveness and uniformity of the skills acquired by medical device professionals across Europe, in response to the expectations of the MDR/IVDR but above all of patients and healthcare professionals.

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REFERENCES

- Bouteiller D, and Patrick G. (2016) "The dissemination of competency-based management tools in North America since David C. McClelland." *Relations Industrielles/Industrial Relations*, vol. 71, no. 2, spring 2016, pp. 224+. *Gale Academic OneFile*,
- Boyatzis, R.E. (1982). *The competent manager: A model for effective performance*. New York: John Wiley & Sons.
- Boyatzis, R. E., & Sala, F. (2004). Assessing emotional intelligence competencies. *The measurement of emotional intelligence*, 2, 147.
- Regulatory Affairs Professionals Society (RAPS) <https://www.raps.org/welcome/raps>
- EUR-lex (2017). Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.). <http://data.europa.eu/eli/reg/2017/745/oj/eng>
- International Organization for Standardization. (2020). ISO 14155:2011 Clinical investigation of medical devices for human subjects-Good clinical practice. <https://www.iso.org/cms/render/live/en/sites/isoorg/contents/data/standard/04/55/45557.html>
- Medical Devices Coordination Group (2020). MDCG 2020-16 Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746 November 2020. https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdmg_2020_guidance_classification_ivd-md_en.pdf
- [https://www.iamexpat.nl/expat-info/insurances-netherlands/dutch-health-insurance#:~:text=Premie%20and%20eigen%20risico%20costs&text=The%20%22own%20risk%22%20amount%20\(a%20maximum%20of%20385%20euros](https://www.iamexpat.nl/expat-info/insurances-netherlands/dutch-health-insurance#:~:text=Premie%20and%20eigen%20risico%20costs&text=The%20%22own%20risk%22%20amount%20(a%20maximum%20of%20385%20euros)
- Syndicat national de l'industrie des technologies médicales (SNITEM) https://www.snitem.fr/fiches_metiers_dm/responsable-affaires-reglementaires/