A Skill based Educational Program for Future Regulatory Affairs Professionals in the Medical Devices Industry: A Top down Approach at Polytech Lyon University, France

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Abstract: The Medical devices industry is facing a shortage in the professionals in Regulation Affairs who are in charge with the regulation steps to bring their MD to the market. The Master ATRDM at Polytech Lyon 1 University, France, was elaborated following a top-down approach based on the development of competencies of the learners, with an agile iterative process to update the contents.

1 INTRODUCTION

The industry of Medical Devices (MD) is facing a shortage in Regulatory Affairs (RA) professionals. Medical Devices need professionals to fulfil each step of the agreements, in order to obtain the CE Marking and to deliver their MD in the market. The transition from the directive on MDs (MDD 93/42) to the regulation on MDs (MDR 2017/745) challenges manufacturers because new requirements require an added budget and human resources for manufacturers and other actors in the medical device supply chain (Bayrak, 2022). Therefore, the MD industry is seeking for professionals in charge of RA for qualifying their MD. The notified body are also seeking for specialists to run the audits of MD devices organisations.

Although in the past, the persons in charge with RA were partially the professionals in charge of the Quality Affairs (QA), the RA of MD has strongly specialised with the MDR and needs the professionals to go through a specific training.

Furthermore, the person in charge with RA of MD needs to be able to drive the project of bringing the MD on the market, involving various actors from Marketing, from RTD, from QA, etc. Therefore, the MD-RA professional needs to develop transversal skills in communication and project leadership.

In the global context of the impact of human activity, the MD-RA professional must consider the sustainability of the production of their MD and its carbon impact.

Actually, there is a plethora of training companies - universities and private operators - offering MD-RA contents. At Polytech Lyon, the School of Engineering of University Lyon 1, we have developped a 'top-down' approach starting with from the identification of the various skills needed by the future MD-RA professionals.This approach is at the heart of the Master Degree “Affaires Techniques et Réglementaires du Dispositif Medical” (Regulatory and Technical Affairs for MD) labeled ATRDM.

2 CONTEXT OF THE MEDICAL DEVICES REGULATION

The MDR 2017/745 (MDR, 2017) comes with stronger requirements and is more demanding that the MDD 93-42-CEE (MDD, 1993).

First the MDR adds more rules to MD than the MDD for considering the development of software, nanomaterials, and combined MD at the frontier between MD and Medicaments.

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Second, the classification of MD, in Annex VIII of the MDR, now includes 22 rules and 80 criteria whereas Annex IX of the MDD contained only 18 rules and 56 criteria. It directly impacts the strategy of classification of the MD. The MDs at higher risks suffer stronger costly controls, but therefore are not accessible to smaller, less competitive, industrial structures.

Eventually, a Post Market Surveillance policy must be settled in order to gather, correct and timestamp each malfunction and non-conformities.

The MDR was not deployed until May 2021 and should be definitively implemented in May 2024 - for MD concerned by a notified body – and 2028 for most MD. But the notified bodies are not numerous enough, and they also lack skilled professionals to face the deadline.

A recent survey by France's leading medical device trade union, SNITEM (Syndicat National des Industriels des Technologies Médicales), showed that 3 out 4 companies in MD are struggling to recruit such regulatory executives.

There is also a huge need for educating the competent professionals in most MD industries to meet the new profile of "person in charge with Regulatory affairs" set out in the MDR.

2.1 QA Versus RA?

Historically, the first professionals in charge with MD-RA were integrated with the Quality Management System (QMS). Therefore, they were mostly located in the manufacturing departments. But the QMS professional is a manufacturing generalist, not specifically MD oriented.

Nowadays, the MD-RA manager must be involved in each step of the life-cycle of the MD. And because the Regulatory requirements are continuously evolving, he must stay informed and be dedicated to the MD-RA. Of course, in small organisations (SMEs, start-ups), there is a strong temptation for the "Swiss knife approach" with professionals acting in various domains. Therefore, MD-RA certified professionals are needed.

2.2 Executives Versus Managers?

Although the management of MD-RA may look like a "filing-forms" tasks, actually the person in charge with MD-RA has a wider field of action, interacting with all the department of companies from research and development to the marketing department. The MD-RA professional impacts the strategy of the MD company. He must have a global vision of the life cycle of the MD, starting with the marketing, preclinic and clinic studies, supplies, manufacturing, controls, marking, packaging, logistic, reconditioning…

To bring a MD to the market is a project. Therefore, the person in charge with MD-RA must be a project leader, interacting with various stakeholders from various departments in the company, e.g. commercials, buyers, quality management and control. The function of MD-RA can be seen in terms of entrepreneurship as he is involved in creating value. Nevertheless, there is still a need for MD-RA officers assisting the MD-RA entrepreneurs. The later can be internal officers, becoming operational after a short training.

2.3 Cross-Functional vs Longitudinal Approach to the MD Life Cycle

The MD specialist must have a global vision of the life cycle of the MD. Starting with the knowledge of the regulatory texts, the MD-RA professional must also understand the various technologies involved in the large domain of the MD (physics, electronics, chemistry, materials, informatics) and their principle of actions on the pathology, in order to be able to perform the analysis and mitigation of the risks associated with the use of the MD.

The MD professional must be aware of the economic aspects of the MD market and the health ecosystem economy, which obviously follows specific rules.

He must know the manufacturing processes, including the supply chains, and the QMS, in order to interact smoothly with them professionals.

Some additional knowledges concern the MD marking technics, the logistic for maintaining the integrity of the MD and the sterilization if needed. Also, the end of life of the MD with reconditioning.

On top of the knowledges, the person in charge with MD-RA must behave as a project leader. He needs to be familiar with management tools and methods. He needs communication skills, in particular oral presentation skills. He needs the skills for piloting the project meetings. He also needs to know basics of crisis management.

3 METHODOLOGY

3.1 Identification of the Skills for Future RA Executives?

When designing a new curriculum – leading to a

professional qualification - the architect of the curriculum must start with considering the objective of acquisitions in terms of skills and competencies (Makulova, 2015). Only then should he consider the knowledges (contents) that learners will need to acquire.

The need for training, anticipated in France in a proposal from CSIS (Conseil stratégique des industries de santé), was defined in 2020 by a national working group led by the MESRI (Ministère de l'Enseignement Supérieur, de la Recherche et de l'Inovation) with numerous stakeholders (SNITEM, Conférence des doyens de Pharmacie, Conférence des écoles d'Ingénieurs en biomédical, EUROPHARMAT, Tech4Health network, Inserm F-CRIN clinical research infrastructure, Association des étudiants en pharmacie, etc.), and has been endorsed by both the French Ministries of Health and Industry.

From these recommendations, we propose the following list of skills which we consider essential for future RA executives in the MD industry.

Firstly, the learners should be able to understand and mobilise a wide range of scientific and technical knowledge in the field of MD, to identify and translate regulatory requirements into product requirements, compliance actions and marketing strategies. To achieve this, they will need to be able to keep abreast of scientific, technological, and regulatory developments, in order to acquire and apply new knowledge and know-how, including in the field of medical practices.

They will need to collect and interpret data to identify and solve problems. To do this, they will need to know how to gather information, analyse a complex situation and update the regulatory text database.

Because the accreditation process of a MD is a project that involves a wide range of professionals, they will need to know how to manage a team. To do this, they will have to implement a project methodology. They will have to manage risks, uncertainties and regulatory constraints. In addition, they will have to implement a continuous improvement approach.

They must be able to communicate orally and in writing in French and other languages - including English - both face-to-face and remotely. They will be required to practise interpersonal communication adapted to each professional context, and to know how to interact in a group.

3.2 How to Bring the Skills to Future RA Executives?

It comes naturally with bringing the theory from experts in the main domains of Medical Devices and Regulatory Affairs. Then the learners will have to do practical exercises on selected academic cases, under the direction of experienced professionals. And on top, the learners must alternate with a professional practise in the RA department of a MD company during 12 months of their education.

3.3 How to Evaluate the Acquisition of the Skills?

The question of evaluation is central in the approach of competences because educators need to deliver degrees to the right person. It is of major importance that the graduates be involved in their own evaluation so as to feel involved in their education process, rather than only lean back on their experienced teachers.

Formative evaluations must be provided so that learners can practice in autonomy along their learning paths to evaluate their own progression (e.g. MCQS - Multiple Choice Questions and Solutions).

A useful method to evaluate the acquisition of knowledge, is solving professional situations through their students' projects. Their productions are usually evaluated from a written report and oral defense in front of their peers.

Eventually, individual terminal examinations must be set to evaluate both the knowledge acquisition (contents) and their capacity of synthesis.

At the end of their 12 months apprenticeship, a final oral defense in front of professionals of the domain of MD-RA, is compulsory to evaluate their implication and their ability to communicate efficiently. It is useful that their peers will be invited to listen to other's presentations to learn by example, and also to develop their own skills through the evaluation of each others' production.

3.4 How to Maintain a Sustainable Employability?

A main pillar of professional education at University, is to prepare the future graduates with a solid background of knowledge, to be prepared to face the constant technical evolutions of their professional domain. Also, to bring to the future graduate the soft skills which will guarantee him with flexibility and adaptation to the evolutions of his professional activities.

Actually, the engineering pedagogy for professional domains is facing 2 contradictory challenges:

- To produce professionals in order to face immediate needs in industry

- guaranteeing the future of graduates in a rapidly evolving professional world

The Methodical approach that we put in practice consists in:

- Bring a wider range of knowledge (than needed for graduation)
- Bring information on the latest technologies developed in research labs, by researchers who show the orientations to follow.
- Take a step back on the needs
- Help the learners to draw perspectives on their own skills
- familiarize the learners with the concepts of Soft-skills vs Hard-skills

3.5 Recruit the Right Learners?

Obviously, the learners shall be recruited from their academic skills (biography, academic results) and their motivations (written letter, personal professional project).

Furthermore, after a selection of the best profiles from their written elements, it is essential to conduct individual interviews to address the non-technical skills of future learners.

In the particular field of MD-RA, a key point is to mix the backgrounds of learners (engineers, pharmacists and biologists). Also, the diversity of profiles gives usually some good results when involving both young learners and retraining professionals.

The building of a team of learners is of utmost importance from the beginning. Each member playing a role in his own education but also acting on the learning paths of their peers. The students projects are good opportunities to challenge the students.

To strengthen the team spirit (team building), social events must be organized, such as after-work parties and visits to industrial establishments. The alumni network is also a structuring tool. Newcomers should be encouraged to join the network quickly, so that they can experience what it's like to belong.

4 THE MASTER ATRDM AT POLYTECH LYON SCHOOL OF ENGINEERING

4.1 The Polytech Lyon School of Engineering

Polytech is a network of 16 public schools of engineering from 16 French universities. It graduates annually 4,200 students and already has 90,000 active graduates. The Polytech Network covers 12 engineering domains (energy, electronics, electrical, applied mathematics, Information Technologies, biology, Biomedical, Civil, material, environment, industry) with 100 specialties (6 specialties at Polytech Lyon: Biomedical, MD-RA, IT, Materials, Mathematics, Mechanics, Robotics).

Polytech Lyon is the School of Engineering of Claude Bernard Lyon 1 University and member of the Polytech Network. Polytech Lyon, as a full part faculty of Lyon 1 university, also proposes Master Degree as a specialization of its Engineer Diploma.

The Polytech Lyon Biomedical Engineering Department graduates Engineers and Master (Perrin, 2007). Considering the wide spectrum of MD, the need for MD-RA is to train Engineers, Scientists and Pharmacist, and this is naturally achieved with a strong collaboration with Lyon 1 Faculty of Pharmacy (ISPB).

4.2 A Time-Based Organisation

The Master ATRDM (Noury, 2022) covers a 12-months training period alternating between a professional activity in a private company and the academic training in university. The later consists in 300 hours of face-to-face education and 150 hours of projects. The projects playing an important role in skills acquisition and evaluation. During the Fall Semester (September to February), the rhythm of alternation is 3 days of training each week and 2 days in the company. After the academic evaluations in February, the students start the Spring semester which consists in a full-time professional education in their companies. In this last period, only 3 days each month are dedicated to projects of student in groups in the University.

4.3 An Elaborated Curriculum

The curriculum is based on a core education on the MD-RA and side trainings.

The core education on MD-RA (140h) is composed of 3 parts:

- The generalities of the ecosystem: industrialists, organizations, stakeholders, notified bodies, understanding requirements,
- Regulatory Aspects: MD classification, European standards (MDR 2017/745, 93/42/CEE), Risk Analysis, clinical evaluations, UDI, PMS…
- Technical aspects of various MD: materials, active electronics, implantable, software, combined

The side (corollary) trainings (160h) covers complementary aspects:

- Project management
- Quality management (ISO 13485)
- Legal aspects: Contract laws, Competition law, Best practices, Sunshine Act
- Security aspects: clinical evaluations, materio-vigilance, radio-vigilance, reacto-vigilance, traceability, PSUR, Risk management (ISO 14971), electro-devices (IEC60601-2-62), software (IEC62304), GDPR, Biocompatibility (ISO 10993)
- Economy of MD: the French Health system, Hospital Purchasing, pricing of MD (Market price), reimbursement, Market Access
- Data strategy: Stake and approach of the company's strategic information management, patents, lobbying,
- MD Regulatory in other countries (US, China, , Canada, Brazil, Japan, South Korea, Australia, …)
- And of course, Professional English practice.

4.4 Evaluation of the Skills Acquisitions

Following the methodology introduced in section 3.3, the evaluations are done through formative evaluations, individual examinations and professional situations during the students' projects.

The first "individual project" focuses on the study of the Technical and Regulatory aspects of a selected Medical Device. The learners must demonstrate they were able to gather relevant scientific and technical information to explain how the MD operates and what is its "principle of action" on the patient, with the targeted population, and to produce an analysis of the risks associated with the use of the MD. Then they must collect the complete book of regulations associated with the lifecycle of their MD, including the classification strategy.

The second one is a "Group project", namely "Bring an innovative MD on the Market". On top of the technical aspects of the technical file, the group of students must address the European Regulatory Aspects and the regulations in one or several other countries (USA, Middle East, Asia, Russia, Africa…). This project also includes "entrepreneurial" aspects such as a market analysis. In addition, the group is evaluated specifically on the elaboration of his project management strategy, and his QMS plan.

4.5 Master ATRDM in a Few Figures

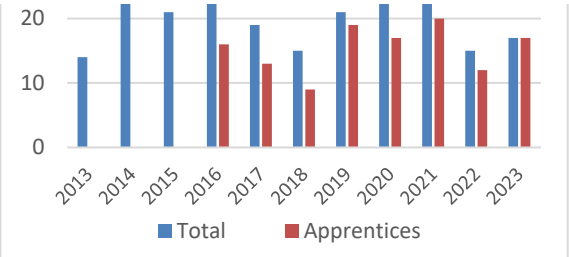

Figure) and their majority are now active in the RA departments of the MD industry in France.

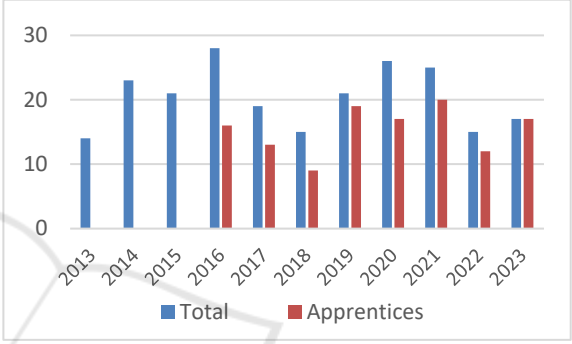

Figure 1: Demography of learners in Master ATRDM.

5 CONCLUSIONS

The elaboration of the academic curriculum of Master ATRDM at Polytech Lyon, is following an Agile development process with annual iterations (e.g MDD→MDR). This is compulsory because the MD-RA evolve frequently and also because the missions of MD-RA managers are constantly changing.

It was based on an important Partnership with professionals from the industry of MD and with SNITEM, the main union of the French MD industry.

Networking between students is strongly encouraged through projects and with their individual adherence to our private group on Linkedin (Alumni, 2016).

Each student is closely monitored by 2 tutors, including a company tutor and an academic tutor from the university. They correspond with each other via an electronic website and during compulsory visits in situ.

We participated in 2013 to launching the French national network of Masters in Regulatory Affairs, Quality and Clinical evaluations of MD (ARClimed project) under the auspices of the AMI-CMA, a French national initiative to foster the development of

new training programs for new occupations in the digital industry. We can now envision a possible European deployment of our Master in MD-RA.

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