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Good practices systematization for medical equipment development and certification process: A Brazilian case study

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ABSTRACT

Medical equipment development requires from manufacturers a clear definition of the processes to the core team in order to achieve the user safety. Therefore, considering the lack of a specific product development framework for medical equipment that meets the Brazilian scenario, this work proposes a good practices systematization for medical equipment development. It covers the main Brazilian regulations that impact on development process of these products. Based on the stage-gates process, the systematization proposed divides the development process activities into five phases and nine functional groups. To each functional group is presented the activities expected to be practiced in each phase, tools that could be used, and the regulations that could guide the execution of the activities. The case study method was used to validate the systematization. Three companies of medical devices were presented to the model and their realities of the development process were compared to the proposed systematic. From the results was possible to conclude the potential use of the good practices as a guide for the process development of health equipment. Besides that, the model allows to follow up the regulations that should be used and can be used as training material.

Introduction

Health products possess specific characteristics when compared to products from other sectors. In the design process, several certification steps must be followed to be able to launch a product in the market. These rigorous regulations aim to ensure the safety and good performance of health products.

Despite being an extremely regulated market, failures still occur in a product development (PD) process, resulting in a product that does not completely satisfy the intended purpose. Defective products released in the market can lead to their recall or even product prohibition, directly affecting the value of the brand and diminishing the investor confidence [1].

The development of a medical equipment (ME), besides having to satisfy the customer, market, and organizational needs, must also meet the regulatory requirements, which affect the entire development process, manufacturing, marketing, and continuous improvement initiatives [2,3].

In a study, Intertek [1] revealed that 90% of ME do not meet the regulatory requirements in their first certification attempts. Failure to comply with these requirements can delay the market entry, increase the costs, and reduce the product profitability as well as put the brand at risk. Consequently, for these industries, modeling the PD process is a regulatory need.

Some studies [2–7] address the PD process for health products according to the US or European demands. These studies present models including good practices, particularly for an ME development process.

However, there is a dearth of studies and scientific articles related to the PD process for medical devices in Brazil [8]. Moreover, the lack of a PD model for MEs in accordance with the Brazilian scenario leads industries to use tools and models from other sectors, which need to be adapted to fulfill the ME specifications, as stated by Almeida [9].

Brazilian ME companies have some specifications regarding their operational characteristics. Their products are mostly of medium to low technological complexity because technical regulations present a major barrier to more complex developments [10]. They are also mainly small and medium-sized. The infrastructure required to be built by these companies must meet the required regulations, which is a major barrier [11].

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Table 1
Comparison of the models.

Authors	Strengths	Weaknesses
Das e Almonor [4]	- Core team formation - Concurrent engineering - Attribute-driven specifications	- Does not address the risk management
Alexander e Clarkson [5]	- Design tactics to help the verification and validation process	- Does not address the regulatory requirements - Does not address the core team formation
Aitchison et al. [6]	- Verification steps between activities	- Risk management slightly addressed
Pietzsch et al. [3]	- Applicable to all medical device classes - Identification of functional groups involved in the process	- Risk management slightly addressed
Medina, Kremer e Wysk [2]	- Link between activities of the models	- Requires knowledge of UML language - Phases do not occur in any order
Qin et al. [7]	- Multidisciplinary team - Focus on design development	- Does not address the development process as a whole - Does not address risk management

Although the domestic demand for ME is increasing, the characteristics of the associated industries generate a trade deficit scenario, with their import covering much of the internal demand [10,12]. One particular characteristic relates to the lack of a clear PD process for the Brazilian scenario [13].

Botrugno [14] emphasized the need for an adequate European regulatory framework to address the design of innovative services in healthcare. According to this author, a regulatory framework could be used to guide professionals toward the best use of innovative healthcare services, leading to a positive impact on the standardization in EU healthcare. This gap identified in the above-mentioned study, motivated this research. Therefore, the aim of this study is to systematize good practices for ME development, covering the main Brazilian regulations regarding the certification process and their impact on the PD process.

We believe that this systematization will assist the Brazilian health care industry to be more assertive in their development process and product certification, avoiding rework in the final development stages.

Methodological procedures

To achieve the objective of this study, two procedures were followed. First, we conducted a systematic literature review to investigate the best practices based on PD process models, and second, we performed multiple case studies with three Brazilian ME companies.

Literature review

The objective of conducting the systematic literature review was to find the already reported models and good practices that directly address health products. Table 1 presents a summary of the models found, highlighting their strengths and opportunities for improvement.

The only model that does not address the subject of team formation in product development was that of Alexander and Clarkson [5]. All the other models emphasize the importance of forming a team with both engineering and clinical expertise.

Compliance with regulatory requirements is a major concern of ME manufacturers. Except for the Alexander and Clarkson model [5], all the others acknowledge the need to comply with the associated regulations. Nevertheless, none of the models provides further details regarding the standards or requirements to be satisfied.

Performing risk management (RM) in the PD process enables a reduction in the product launch time, more confidence in meeting the regulatory requirements, and reduction in product failures [1]. Despite its relevance, neither Das and Almonor [4] nor Qin et al. [7] address this topic. Even the authors who discuss RM, do it superficially. The Pietzsch et al. [4] and Aitchison et al. [6] models, for example, do not address all the steps for RM.

The analysis of these models reveals the need for a new model that is simple and easy to understand and apply [15]. The Medina, Kremer, and Wysk [2] model may be considered impractical for small to medium organizations. This model, for example, requires prior knowledge of the *unified modeling language* (UML) and expertise to distribute the recommended PD activities in the stages of the development process.

Table 2 presents the macro activities identified by each model and how they address the waterfall model required by the FDA [16].

Not all the models cover all the phases of the cascade model. The Das and Almonor model [4] does not present a macro activity dedicated to identifying the user needs. The Aitchison et al. model [6] describes the “Design Process” macro activity as being responsible for defining the project concept and product details. This activity is related to both the “Project Inputs” and “Development Process” of the FDA model. Qin et al. [7] used his model to develop a single product, and therefore, did not incorporate the stage of “Medical device”. This FDA stage addresses device production until the product is launched in the market.

Case study

The case study procedure adopted herein followed the Yin [17] and Miguel [18] methodologies. According to Yin [17], a case study should be performed when the purpose of the research is to deepen the knowledge about a problem that is not sufficiently defined in the literature, as is the case of this work. This method is appropriate to investigate two aspects of a phenomenon: "how" and "why" it happens. The phenomenon studied in this work is an ME development process that must address the Brazilian regulations. Therefore, we performed a case study to verify the adequacy of the proposed systematization for the organizational scenario in the medical sector.

To conduct this case study, the steps proposed by Miguel [18] were used: define a theoretical conceptual framework for planning the cases was defined, the cases were selected, the data were collected, the data were analyzed, and the report was generated. The theoretical conceptual framework resulted from the systematic literature review phase.

The criteria used to select the companies were the size of the company and type of equipment developed. Seventy eight percent of the national companies are either micro-, small-, or medium-sized, with medium-large and large ones accounting for the remaining 22% of the market [11]. This led us to select one micro, one small, and one medium-sized company, presented in Table 3 with their characteristics.

Irrespective of the company size, all the products are Class II, which limits the study mostly regarding the clinical test procedures. Another limitation is in the small sample size used.

Table 2
Comparison of the macro activities of the models.

Authors	Waterfall model [16]				
	User needs	Design input	Design process	Design output	Medical device
Das e Almonor [4]		- Concept proposal - Form core team - Create attributes - Project plan	- Design process/Design control/Documentation	-Regulatory approval -Process validation -Clinical validation	- Release product
Alexander e Clarkson [5]	- User needs	-Design inputs	- Design process	- Design output - Process needs - Process design - Product's verification and validation - Process's verification and validation	- Production - Medical device
Aitchison et al. [6]	- Feasibility	- Design process		- Verification - Manufacture - Validation - Design transfer	- Design changes
Pietzsch et al. [3]	- Initiation / Opportunity and risk analysis	- Formulation / Concept and Feasibility	- Design and development / Verification and validation	- Final validation / Product launch preparation	- Product launch and post-launch assessment
Medina, Kremer e Wysk [2]	- Clinical need definition and team formation	- Feasibility, risk assessment and conceptualization	- Detailed design, verification and validation	- Production planning and qualification	- Market introduction and post-launch
Qin et al. [7]	- Client requirements	- Research and analysis	- Design sketching - Computer modeling	- Prototyping - Assembly, labeling, clinical testing	

Table 3
Case study companies.

Company	Size	Age	Interviewee	Certification	Product features
A	Micro	09 years	Director	- ISO 13485	- Electric patient lift - Class II - Certified and commercially available
B	Small	12 years	Project Manager	- Good Manufacturing practices by ANVISA	- Wireless electrocardiograph - Class II - Final development phase and certification preparation.
C	Medium	10 years	Director	- ISO 9001 - ISO 13485	- Digital autoclave - Class II - Certified and commercially available

We performed semi-structured interviews to collect the data. Key personnel working in the PD process of each company were interviewed. We targeted the PD personnel who were the most experienced in the team and those in charge of the PD process.

To obtain the information, the researchers not only conducted interviews but also performed on-site observations and a deep documental analysis. It is worth emphasizing that these multiple sources of evidence were essential to ensure the reliability of the collected data and increase the validity of our research [19]. Finally, the reports generated from the multiple case studies were sent to the interviewees for a double analysis and potential adjustments of the responses.

All the case studies followed the same rationale and interview protocol. First, the researchers collected information about the company and PD process, asking the interviewees to typically refer to the development process of a single product of their choice. Then, the proposed systematization was presented, and the phases, macro activities, functional groups, and activities were explained. Finally, the interviewees answered the questions regarding the verification and validation of the systematization. Appendix A presents the interview protocol used.

We applied the first validation level proposed by Smith and Morrow [15]. In this first level, the model is evaluated by the personnel familiar with the PD process, who in our case were also those responsible for the PD process. This evaluation allowed the validation of the adequacy of the proposed systematization for the scenario of the studied companies.

The other validation levels required the instantiation of the proposed systematization for an actual ME product developed, throughout the development process. Therefore, the lengths of time required to perform these levels prevented their application.

Good practices systematization for ME PD process

Smith and Morrow [15] argued that a PD model should: (i) address management issues; (ii) be based on available and up-to-date information for decision-making; (iii) be simple to be used as an abstraction of the actual process. Using their recommendations and the literature review findings, we propose systematization for the ME PD process that among other activities and good practices can:

- Present the regulations to be followed, given their relevance in the Brazilian certification process;
- Provide RM, owing to its importance in ensuring product and user safety and organizational strategy;

Our good practices systematization for the ME PD process used as a reference the *stage-gate* model of Cooper [20] and its application in the ME development by Pietzsch et al. [3].

We divided the ME development into seven macro activities, grouped into five phases and four decision *gates*. The phases are:

Phase 1. Opportunity analysis: verification of the gaps in the market in which the company can position the new product;
Phase 2. Conceptual feasibility: design and selection of the new product concept;
Phase 3. Project inputs and outputs: product development, considering user and regulatory requirements;
Phase 4. Project Verification, Validation, and Transfer: verification of the product developed according to Phase 3 requirements, and validation of the user needs. Submission for regulatory approval and transfer to the production line;
Phase 5. Product launch: sales and post-launch monitoring efforts.

The macro activities were based on the steps listed by the models studied in the literature review presented in Table 2. We used the same terminology for the macro activities as those in the ABNT NBR IEC standards [21–25].

Based on their characteristics, we grouped the activities into functional groups, similar to Pietzsch et al. [3], and we followed the same rationale of PMBOK (Project Management Body of Knowledge), which divides project management activities into "knowledge areas" and the CMMI (Capability Maturity Model Integration) into "process areas" [26]. The proposed structure includes nine functional groups: 3.1 Management; 3.2 Marketing and Sales; 3.3 RM; 3.4 Research and Development; 3.5 Regulatory; 3.6 Manufacturing and Operations; 3.7 Quality; 3.8 Clinical; and 3.9 Patents.

For each functional group, we present the expected activities that should be performed in each PD process phase together with the regulations that must be followed. Based on their characteristics and requirements, the regulations were distributed among the activities proposed by the functional groups.

In the *stage-gate* process, at the end of each phase, there is a *gate* decision in which a team of representatives from the areas involved in the process evaluates whether the project should move to the next phase, be aborted, or demands further modifications. The input information of a *gate* is the deliverable of the previous phase, whereas the output is the decision regarding the project continuation and action plans [20].

For the project status definition at the *gate* exit, the involved team must define the criteria for its decision judgment. These criteria vary for each organization according to its development strategy. Based on the activities involved in the ME PD process, Fig. 1 presents the proposed deliverables and decisions to be made at each *gate*, and their evidence from the literature.

It is important to emphasize that although the activities are defined in the development phases, the process of creating a new product is continuous, being iterative and interactive between the functional groups, and therefore, it is impossible to delimit the activities in a phase. The same concept must be applied to documentation, which needs constant updating.

Owing to the vast scope of an ME and the complexity of its development, it should be noted that the proposed systematization is limited to ME equipment, does not address processes and regulations for reconditioned products, and does not consider software development.

Fig. 2 presents the proposed systematization. The functional groups are detailed in the following sections.

Management

Oliveira et al. [8] argued that managing a project effectively is crucial to producing safe and effective products. Therefore, one requirement of ME certification is an adequate planning process.

Furthermore, the project team should be multidisciplinary, with representatives of all the areas involved in the project [2–4,6,7].

Marketing and sales

The activities of this functional group begin with the market evaluation and potential of competitiveness for the proposed product.

The customer (or end-user) participates in the PD from the initial stages until its validation. In the final stages, the focus shifts to prepare the market to receive the product through the sales plan and training of the user who will use the product.

Risk management

RM anticipates and reduces the possibility of failures and their consequences, becoming a critical element in development [3,8]. In addition, it is possible to reduce the costs and product launch time and be more assertive in the regulatory submission [1].

Addressing risk assessment from the earliest stages is much more cost effective than from the later stages as the products and processes are still under development. This leads to a relatively lower modification cost [5].

Research and development

Aitchison et al. [6] stated that the norms and regulations also define the design requirements. Therefore, this functional group is the one with the highest number of regulations and norms.

In the first phase, the team must consider both the customer and regulatory requirements to develop the conceptual design. Only in phase 3, the requirements and equipment characteristics are detailed.

In the product verification and validation phase, the electromagnetic compatibility must be ensured [27].

Documents such as the Project Historical Record and Product Master Record must be continuously updated as they are the RM audit target in the product conformity assessment process.

After launching the product in the market, the research and development activities shift their focus to product improvement.

Regulatory

Problems in the final stages of the PD process can be avoided by identifying the regulatory norms and requirements from the early stages of development [6]. The team should consult the regulations presented in the systematization and any other specifications for their product.

Even after the product is in the market, the manufacturers are responsible for the post-market surveillance of their equipment. They must have a system for adverse event surveillance and technical complaints post launch [28].

Manufacturing and operations

From the project start, the team must consider the manufacturing and assembly issues to avoid reworking in the advanced stages of the development. Thus, the design for manufacturing (DFMA) and process FMEA (PFMEA) are extremely important for product evaluation.

When the product is in the validation phase, efforts in the manufacturing and operations become more intense with the objective of ensuring that the production processes and supply network meet the sales demands.

Quality

This functional group must accomplish most of its activities before the final stages of the development, when the product is

GATE 1	GATE 2	GATE 3	GATE 4
Deliverables (source)			
• Financial forecast [2,3] • Preliminary assessment of the technical risks [2,3] • Initial financing strategy [2,3] • Business plan [2,3] • Preliminary assessment of the intellectual property landscape [2,3] • Evaluation and validation of the needs [2,3] • Competitiveness analysis [2,3]	• Creation of project historical record [RHProj] [2] • Product master record creation [RMP] [2,3] • Risk management file [none] • Identification of the specifications [2,3,4,5,6] • FMEA [and its variations] [2,3,4,5,6] • DFX [DFMA, DFE] [2,3,6,7] • Project team definition [3,4] • Intended use [2,3,4,6] • Regulatory plan [3] • Design and development plan [2,3,4]	• Verification protocol, tests and reports [3,6] • Clinical research plan [2,3,6] • Manufacturing validation plan [2,3,4,5] • Manufacturing plan [3,5,6] • Packaging, labeling, and storage definitions [7] • Technical specifications [2,3,4,5,6,7] • Testing for regulatory submission [2,3] • Schematic drawings [2,3,4,6,7]	• Risk management report [3] • Manufacturing verification [5] • Verification of the complete project [3,5] • Manufacturing validation [3,5] • Documents for beginning sales [catalogs, advertisements] [2,3] • Validation of the complete project [3,5,6] • Qualification of the suppliers [3]
Decisions [source]			
• Is there a market opportunity? [2,3] • Is there a definition of the risk class? [2,3] • Is the project ready to move from active project status? [3,4] • Is the project risk from the point of view of intellectual and regulatory property acceptable? [2,3] • Is the product in line with the company strategy? [2,3]	• Has technical feasibility been proven? [3] • Is the product ready for the beginning of its development? [3,6] • Have the manufacturing and supply chain been evaluated? [3]	• Is the design frozen? [3] • What is the manufacturing strategy [3,4,5] • Does the design meet the manufacturing specifications? [3,5,6] • Are the residual project risks acceptable? [3,6] • Is there any infringement of intellectual property? [3] • Is the product ready for regulatory submission? [2,3,4]	• Do the tests verify the product? [3,5] • Is the inventory level adequate to meet the sales? [2,3] • Do the tests validate the product? [3,5,6] • Is the product ready for marketing regarding the legal and regulatory issues? [2,3] • Are the design and manufacturing risks acceptable? [3] • Are the sales representatives trained to launch the product? [2,3]

Fig. 1. Deliverables and decisions of the gates.

transferred to production. Subsequently, the quality team must evaluate the quality of the products, processes, and inputs.

Even after the product is already launched, the processes and monitoring of the product quality should continue.

Clinical

This group focuses on the clinical trial activities for health products with class III and IV risk [29,30].

Clinical trials are planned when the product is moving out of the development phase and starting the verification and validation phase. It comprises of two sub-phases: pilot and pivotal. In the pilot phase, the test establishes the product safety and initial efficacy parameters and assists in the pivotal study criteria development. The pivotal phase confirms that the product is safe and effective for the intended use [31].

Patents

It is important to analyze the intellectual property before starting the development to verify any existing patent on the product, its components, or the process. Depending on the findings, the risk assessment assists in verifying the project feasibility, as recommended by Pietzsch et al. [3].

Besides this verification, it is also important to identify patent opportunities for the product under development. According to

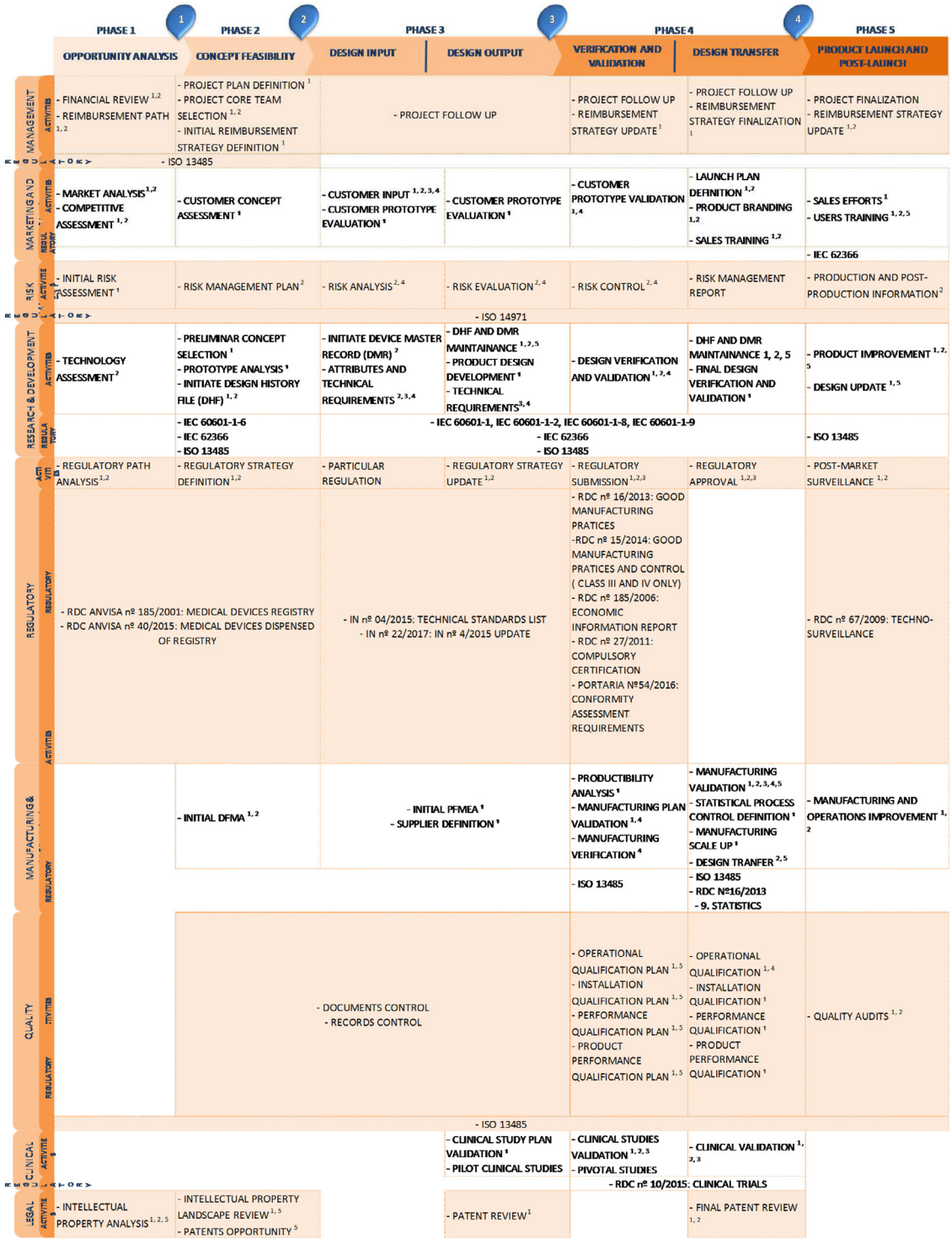

Fig. 2. Good practices systematization for the ME PD process.
Note. 1-Pietzsch et al. [3], 2-Medina, Kremer and Wysk [2], 3-Das and Almonor [4], 4-Alexander and Clarkson [5], 5-Aitchison et al. [6], 6-Qin et al. [7].

Aitchison et al. [6], protecting products through patents has an important role in its success, and therefore, should be considered from the earliest stages.

Results

The importance of the proposed systematization is evident from the results of the case studies. It is noted from the three case studies that the companies that do not have a defined PD process make their decisions empirically, through informal processes, showing an immaturity in their process management. The small number of records and documents that formalize the decisions of the development process is at the expense of the regulatory force rather than of the understanding of companies of the importance of the PD process.

Companies have difficulty in maintaining up-to-date documentation during the entire PD process. Therefore, it is necessary for organizations, even with a few employees, to establish strategies

Table 4
Comparison of the case studies based on the proposed systematization.

	Company	Phase 1	Phase 2	Phase 3		Phase 4		Phase 5
		Opportunity analysis	Concept feasibility	Design input	Design output	Verification and validation	Design transfer	Product launch and post-launch
Management	A	●	●	●	●	●	●	●
	B	●	●	●	●	●	●	●
	C	●	●	●	●	●	●	●
Marketing and sales	A	●	○	○	○	●	●	●
	B	●	○	○	○	●	●	●
	C	●	○	○	○	●	●	●
Risk management	A	●	●	●	●	●	●	●
	B	●	●	●	●	●	●	●
	C	●	●	●	●	●	●	●
Research & development	A	●	●	●	●	●	●	●
	B	●	●	●	●	●	●	●
	C	●	●	●	●	●	●	●
Regulatory	A	●	●	●	●	●	●	●
	B	●	●	●	●	●	●	●
	C	●	●	●	●	●	●	●
Manufacturing & operations	A		○	●	●	●	●	●
	B		○	●	●	●	●	●
	C		○	●	●	●	●	●
Quality	A		●	●	●	○	●	●
	B		●	●	●	○	●	●
	C		●	●	●	○	●	●
Clinical	A				N/A	N/A	N/A	
	B				N/A	N/A	N/A	
	C				N/A	N/A	N/A	
Legal	A	N/A	N/A		N/A		N/A	
	B	N/A	N/A		N/A		N/A	
	C	N/A	N/A		N/A		N/A	

to allow documentation management to run in parallel with the development process, avoiding information loss.

All the data collected from the interviews are reported in [32], and Table 4 presents a summary comparing the activities performed by each company based on the case study with the proposed systematization. The exhibited similarity corroborates with the argument of Pietzsch et al. [3] that the apparent coherence between the PD processes of the companies in this sector can be explained by their need to comply with the regulations that address the quality system.

In the functional group, “Marketing and Sales,” contrary to the suggestion by Das and Almonor [4], the companies do not include the product end-user in the product development (Phase 3). The companies only consider the end-users for the requirement survey (Phase 2) and only consult them again in the prototype validation phase (Phase 4).

Privitera et al. [33] studied some difficulties faced by US and European ME manufacturers to involve the end-users in their PD process. In the Brazilian scenario, although we can identify a low end-user incorporation rate in the development process, further studies are necessary to assert this.

Regarding the functional group, "Risk Management," although all the companies perform the proposed activities, it is possible to perceive that this is a sensitive issue for organizations. The main problem reported is that they do not know how to apply the RM proposed by ISO 14971. Thus, there is an opportunity for further studies in this area to identify solutions that facilitate the understanding and application of the RM standard for health products.

The companies performed all the activities planned in the Research and Development functional group, as presented in Table 4. However, they do not employ a multidisciplinary team to develop their products. Companies cited IEC 60601-1 as a guide for routine testing in their PD process. However, they do not cite other standards that are also compulsory for ME.

The analysis of the "Regulatory" functional group showed that the companies conduct all the planned activities, even considering topics regarding the norms and regulatory issues they must follow. Except for Company B, all others start their regulatory certification after the product and processes are already defined and completed. Even when considering the regulatory issues from the beginning, two companies reported difficulties during certification, delaying their product launch in the market and increasing the costs involved in their development process. This emphasizes the need for companies to have a support system for regulations compliance. In this context, the proposed systematization can fill this gap, helping organizations in this sector to manage compliance with the regulatory requirements.

Companies prefer to develop products with a low embedded technology to achieve the regulatory approvals easily, resulting in a rapid market insertion. This explains the preference for the importation of high-technology products, leading the Brazilian companies to limit themselves to relatively simpler products [10].

The functional group, "Manufacturing and Operations," shows that the companies tend to outsource the processes they deem unnecessary to spend costs. Therefore, manufacturing issues, which are generally outsourced, are not considered from the project start, as shown in Table 4. Companies focus on the internal assembly of the products and vary according to their needs, which are outsourced.

Regarding the functional group "Quality," it is noticed that all the three companies tend to validate the manufacturing and operation processes from the product validation. Therefore, they do not predict any activity for this functional group for manufacturing validation. The main attributes identified for this group are the verification of the tests results and trials generating a product meeting the quality standards and monitoring of the production process.

In this study, it is not possible to validate the "Clinical" and "Patents" groups, particularly the "Clinical" group because Class II equipment do not require clinical testing. The functional group, “Patents,” was not compatible with the scenarios of the companies, although two of them already have patented products. All the three companies point that they have a low interest in patenting

their products owing to the lengthy process and legal insecurity. However, because large companies were not included in the study, we considered important to maintain this functional group as it was based on the literature review, leaving it to the user to choose to apply it.

The companies stated that the proposed systematization considers the regulations they follow in their process of product development and the phases through which the project phases are portrayed. They considered the systematization to be easy to understand and apply, and believed that it could become a guide for the PD process, assist in the assertiveness of external consultancies, and serve as training material for new employees or even for the new companies entering the ME sector.

Discussion

The process for releasing an ME in the market is complex and involves several requirements to prove its performance and safety. We reinforce the need to assist the industries in becoming more assertive in the product development process and certification. This will avoid rework in the final stages of the development because of not meeting the regulatory requirements, which can delay the product launch and increase the development costs.

One limitation regarding the results is from the small sample size, with all the studied companies producing only class II products. However, all the respondents are leaders of the PD in their companies, with their sizes matching those of 78% of the Brazilian companies. Besides interviews, other sources of data are also used, such as observation and analysis of the internal documents, to corroborate with the interviews and increase the data reliability.

Because the systematization proposed here establishes the normative requirements that Brazilian companies must follow, we expect that the organizations of this sector can become more precise in their regulatory process. By evidencing RM as a functional group, we highlight its importance within the ME PD process. For health products, RM is crucial for product safety assurance, essential for product compliance certification, and contributes to the competitive strategy of the organization. A good RM reduces the costs and product launching time, besides ensuring compliance with most of the regulatory requirements.

The major difficulty and concern of the companies is how to meet the regulatory requirements in the absence of any manual or explanation on how to apply the standards. In this respect, the systematization allows us to distribute the normative requirements during the development process. However, still there is a gap for developing methods that facilitate the understanding of the norms and their application in the ME PD process. The systematization proposed here only presents the required standards; it does not explain how to use them.

One noteworthy point is that the current regulations verification change according to the sector regulatory body.

Conclusions

It is possible to perceive the potential of using this systematization to serve as a guide for the PD process for health. Using it, it is possible to verify the phases and activities inherent to the PD process, besides being able to follow the required regulations. In addition, companies can use the systematization as training material, allowing new personnel to learn the ME PD process and its specifications.

The proposed systematization, although complete, is extensive. This may be burdensome to some companies who have a few employees, where the members of development team need to work in different functional groups, becoming overload with several assignments.

Nevertheless, the detail level of the proposed systematization allows a better activity control. This will help the team to avoid overlooking relevant factors that may affect the certification process.

Finally, it is important to emphasize that a PD process is a continuous process, evolving with the organization and practices of developing new products. Therefore, we believe that the proposed good practices systematization will become a general reference for ME development, which could be adapted for a company scenario.

Author statements

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Competing interests

None declared.

Ethical approval

Not required.

Appendix A. Interview questionnaire

Item	Question
1.1. Company characterization	
1.1.1	How big is the company?
1.1.2	How long does the company operate?
1.1.3	How many products launched in the market? Which are?
1.1.4	What is the risk of these products?
1.1.5	Do you export any products? To which countries? Do these require any special registration?
1.1.6	Does the company have any certification?
1.2. Interviewee characterization	
1.2.1	What is your role in the company?
1.2.2	What is your background?
1.2.3	How much company time?
1.2.4	Have you participated in the development of how many products?
2. Product characterization	
2.1	What is the risk class of the product?
2.2	For the development of this product, what level of innovation was required?
2.3	What was the level of expertise of the company in the same technology?

(*continued on next page*)

(*continued*)

Item	Question	
3. Characterization of the product development process		
3.1	Management	Does the company have a clearly defined product development process? Do you have a template to follow?
3.2		What characterizes the beginning of a project?
3.3		What is the composition of the work team?
3.4		What tools were used for project management?
3.5	Marketing	How are users' needs collected?
3.6		What other sources of information complement the entry requirements of the project?
3.7		How is the preparation for entry of the product on the market?
3.8	Risk	At what stage of development does risk management start?
3.9		What tools are used to support this management?
3.10		Who makes up the risk management team?
3.11		What regulation / standard are used for risk management?
3.12	R & D	How is the integration of end-users in the development process?
3.13		What tools are used in the course of product development?
3.14		How is the project documentation done?
3.15		How is the documentation updated?
3.16		How is the design freeze done?
3.17		How is the project transferred to production?
3.18		How is product improvement opportunities identified?
3.19		What regulation / standard are used for product development?
3.20	Regulatory	At what point does the company verify the regulatory path that should be adopted for the product?
3.21		How does the company do regulatory control in the course of development?
3.22		At what point does the company initiate regulatory submission?
3.23		Has the company already had any product that did not obtain the release of ANVISA in the first submission? If so, what is the reason for disapproval?
3.24		Did you get approval later? How long it took? Were there any costs involved? Was there product rework?
3.25		How is the post-market surveillance of products done?
3.26	Manufacturing	At what stage of the development process is the manufacture of the product considered?
3.27		At what stage of development does the creation of the supply network for the manufacture of the product begin?
3.28		What tools are used to evaluate impact on manufacturing in the product development process?
3.29		How is the manufacturing process validated?
3.30		How is process improvement opportunities identified?
3.31		What regulation / standard are used to guide the manufacturing process?
3.32	Quality	What does the company's qualification plan include?
3.33		When do quality audits begin?
3.34		How is complaint handling done?
3.35		What is the role of the quality team before audits of certifying bodies?
3.36		What regulation / standard are used to guide product and process quality?
3.37	Clinical	When is the clinical trial plan defined?
3.38		When to start clinical trials?
3.39		How is clinical validation done?
3.40		What regulation / standard are used to guide the clinical trial process?
3.41		What are the main difficulties for the development of clinical studies?
3.42	Legal	Has any product / process been developed patented?
3.43		Is the path to the patent process well known and well defined?
3.44	Management	Are new projects funded by the company, or is it necessary to use financing?
3.45		When there is funding, is there any relationship between the release of funds and the completion level of the project?
3.46		Are there project review meetings in the course of development?
3.47		What were the deliverables at each stage?
3.48		What is the approval criterion for the next phase of the project?
5. Verification and validation of systematization		
5.1	Does the model allow for the notion of what regulations and standards should be followed for the development of a new product?	
5.2	Does the model allow the overall view of the medical product development process?	
5.3	Could the model be used as a guide for the medical product development process?	
5.4	Could the model be used as training material and good medical product development practices?	
5.5	Does the model presented reflect the reality of the company?	
5.6	Is there any tool used in the company that is not in the model?	
5.7	Is there any functional area not portrayed in the model?	
5.8	Is the model complex?	
5.9	Is the model easy to use?	
5.10	Would you need technical help to use the template?	
5.11	Does the model present terms that require the learning of concepts not used in the work routine?	

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