AN ONTOLOGY MODEL FOR THE MEDICAL DEVICE DEVELOPMENT PROCESS IN EUROPE

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ABSTRACT: Product development refers to the transformation process of an idea into a product or service. It can be applied to any sector, but special attention must be given to each industry particularities. In the case of medical devices, the development process should consider the multiple definitions of the term 'medical device', a vast regulatory framework as well as numerous organizations that evaluate the devices' safety and effectiveness before entering the market. It should also consider various stakeholders and a variety of requirements regarding risk and quality. Currently, literature regarding product development methodologies applied to medical devices is scarce, and there is no graphical representation of the process addressing the environment in which it occurs. Here such representation, for the European market, is made in order to help to understand how medical devices are developed, evaluated and approved. The development process of medical devices was depicted because it is the most practical, easiest and fastest way to maintain, understand and communicate information. Furthermore, it facilitates the identification of the elements driving the process and reduces the complexity of the reality being represented. As the diagram presented is generic, it can be applied to every segment of the medical device industry. In addition, it can be both used by designers and management to guide the process, implement quality standards, support decision and select tools.

KEYWORDS: Product development; Concept model; Graphic representation; Europe; Regulations

1 INTRODUCTION

Product development refers to the transformation process of ideas into commercial products [1]. Typically, it starts with the recognition of a need. Then, the problems that customers aim to solve by buying new products are identified (customer needs). Following, numberless ideas to satisfy the needs are generated but usually only one is developed and optimized. Prototypes or pre-series are produced and evaluated by a restricted number of clients and, if they perform well, the process ends with the launch into the market.

In spite of the differences among product development processes, it is possible to define a generic procedure since they share common tasks and features. The application of such a procedure has many advantages such as facilitate planning, increase predictability, help to improve quality, reduce costs, and compress cycle times [2-4]. However, is possible to obtain further benefits if a dedicated procedure is used, that is, a procedure that considers the characteristics of the product being developed and the environment in which the development occurs.

This paper presents the differentiating characteristics of medical devices and suggests a dedicated product development methodology. The procedure is presented graphically because that is the most practical, easiest and fastest way to maintain, understand and communicate information. Furthermore, it facilitates the identification of the elements driving the process and reduces the complexity of the reality being represented. This representation, besides helping to understand how medical devices are developed, evaluated and approved, will guide both managers and designers during the development process. It will also support decision making, the selection of tools and the implementation of quality standards.

This article is organized as follows. After the presentation of the particular characteristics of medical devices, a review regarding medical devices development methodologies is made. Following, the new representation for the development process of medical devices is described. Finally, conclusions are drawn, and possible future perspectives are indicated.

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2 CHARACTERISTICS OF MEDICAL DEVICES

Medical devices encompass distinct apparatuses ranging from dental floss to lab-on-a-chip technology and are used in different settings, such as our homes and hospitals. They also have several users, i.e., clients, who use the devices differently and with dissimilar expectations [5].

Despite the fact that different definitions for the term 'medical device' coexist, overall, it refers to any apparatus, software or material intended to be used in the diagnosis, prevention, monitoring, treatment or alleviation of a disease or an injury [6]. The differences in the definition reflect the regulatory system with which the devices must comply, which in turn affect the industry performance.

It is possible to classify medical devices according to several criteria. While some categorizations have no impact on the device, others, like the risk classification, determine the legislation the device must comply with and its path to market.

Medical devices interact with human fluids and tissue and as such cannot be disposed like other products. This is one of the reasons for considering carefully the entire lifecycle of the devices during the product development.

To ensure the safety of both patients and healthcare providers, medical devices are highly regulated. During their development regulations, standards and guidelines regarding safety, quality, effectiveness, materials and others requirements must be considered. Besides these documents, there are entities responsible to evaluate if the devices conform. After the device enters the market, monitoring continues to evaluate the risk the device actually poses and to record adverse events; analyses are conducted to determine coverage and reimbursement policies.

3 DEVELOPMENT OF MEDICAL DEVICES

The development of medical devices is both capital and technologically intensive requiring highly qualified personnel with different backgrounds ranging from medical doctors to engineers. It is often the case that design requirements are incomplete and complex, and result from ambiguous situations. Furthermore, the devices' lifecycle is similar to or even longer than the development cycle, and research happens in every direction. These reasons can explain why most commonly the development of novel devices is incremental with each model slightly different from its previous generation [7]. In this section, some of the research regarding methodologies for the development of medical devices is presented.

As the development of medical devices is complex, it is common for regulatory bodies to offer consultancy services to help manufacturers deal with regulations and standards. For example, the British National Health Service (NHS) of the National Innovation Centre (NIC) has available online free-to-use tools to support the development of innovations [8]. Using the 'Scorecard' it is possible to rank ideas and, by browsing through 'Navigator', one can structure the development of a novel device.

In 1997, the FDA (Food and Drug Administration) presented in the document "Design Control Guidance for Medical Device Manufacturers" the waterfall model as a tool for introducing new product design controls. Some years later, the same institution encouraged manufacturers to shift to the total product life cycle (TPLC) model, a holistic approach to managing products through their lifecycle and making improvements to new products based on experiences with current products [9].

In their work, Aitchison et al. [10] described the design process for implantable orthopedic medical devices. The process was represented sequentially with 7 stages separated by design reviews to evaluate design requirements, assess the capability of the design and identify problems.

Aguwa et al. [11] proposed an integrated fuzzy-based modular architecture for medical device design and development. In their work, the development of medical devices involves 4 steps. The first step refers to the functional and physical decomposition analyses of a medical device or system. The second step includes the selection of the performance parameters and the identification of the key metrics. Then, there is the evaluation of candidate modules. This is a phase that consists of two tasks: the development of a formal, structured process for engineering judgment of candidate modules with respect to the selected design objective metrics, and the development of a fuzzy logic model for transforming the subjective judgments into a set of performance indices. The fourth and final stage is product modularization using a multi-optimization model.

A stage-gate process is proposed by Pietzsch et al. [12]. The process includes the following 6 phases: predevelopment activities; opportunity and risk analysis; concept and feasibility; design, development, verification and validation; product launch preparation; and product launch and post launch assessment.

Das et al. [13] propose an attribute-driven concurrent engineering (ADCE) process for the development of medical devices.

Medical devices are a regulated product and, as such, have to comply with multiple standards, regulations and also guidelines regarding varied topics like safety, quality, risk management and others. To overcome this fact, Alexander et al [14] recommend, along with a concurrent engineering approach, the application of design for X methods. Medina et al [15] go further suggesting guidelines to design for FDA (DfFDA) that should be used, when appropriate, with another design for X methods such as design for assembly (DfA), design for manufacturing (DfM), design for reliability (DfR), design for quality (DfQ), design for validation (DfV) and design for usability (DfU). Design for FDA

aims to increase awareness about regulatory compliance and promote designers to consider the regulations throughout the development process of medical devices.
Literature shows that there is a concern in addressing the medical device specificities. However, each author focuses in a single aspect. In the following section, it is suggested an integrated methodology for the development of medical devices.

4 PROPOSED MODEL

Regardless its complexity, every medical device must comply with similar requirements regarding quality, safety and effectiveness. The model proposed here is generic and, as long as it is custom-tailored, it can accommodate the specificities of any device. This model aims to describe the European environment in which medical devices are developed, i.e., indicate the development process' inputs and outputs.
The representation of the development process of medical devices was accomplished in two phases. During the first phase, information was gathered from literature on product development methodologies and medical devices, and the process was implemented using Business Process Model and Notation (BPMN) [16]. During the second phase, the first version of the graphical representation was discussed; several structured interviews were conducted, and an online survey was created and made available among members of academia, industry and regulatory bodies. With the feedback obtained, the model was completed.
As Figure 1 shows, the development of a medical device can be described as a cycle composed of the following phases: idea creation, concept development, design, regulatory approval and clearance, and post-market surveillance and vigilance. The process is highly iterative and the borders of the phases are blurred. In Europe, in order to start the regulatory approval and clearance stage, one has to have the medical device and its manufacturing process completely defined because both the quality of the product and production are assessed.

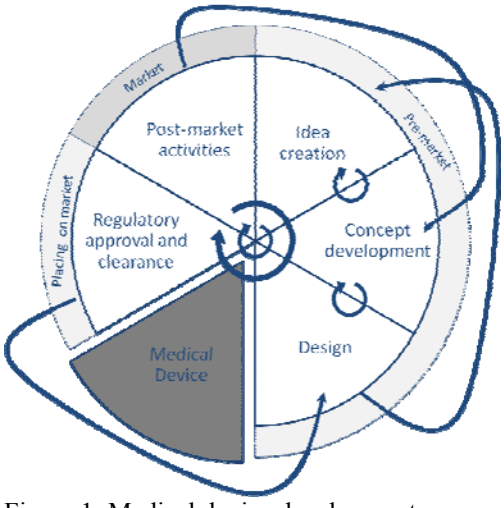

Figure 1: Medical device development process.

Idea creation can be decomposed into several tasks (Figure 2). It can start in various ways ranging from the identification of a clinical need to the identification of a capability, i.e., new knowledge or technology. In order to proceed, not only does the commercial potential of the market opportunity have to be assessed, but also its readiness or, in other words, whether there is suitable technology, the manufacturing process is feasible or the market is prepared. If the opportunity has potential, the development of the medical device has to be planned and a decision regarding the markets in which the device will be commercialized has to be made. This decision will dictate the regulatory framework; here, it is addressed the European one.
The next phase, concept development (Figure 3), is an iterative process that starts with the analysis of competitive products and the voice of the customer, i.e., the process of capturing the customers' expectations, preferences and aversions (Figure 4). The latter is a sub-process that starts with the identification of the customer; in this context, 'customer' represents those that are involved in the development of the medical device, from the maker to the user. During this stage, the management of intellectual property (Figure 5) must be considered constantly to protect new ideas/inventions and not to infringe on existing patents or utility models.
During the design phase (Figure 6), both product (Figure 7) and manufacture (Figure 8) design can be performed either sequentially or concurrently. The management of intellectual property is once again a constant, and the hazard analysis (Figure 9) should be conducted frequently to minimize risks and also to prepare post-market surveillance.
The approval process differs from country to country; Figure 10 shows the European process.
Post-market activities are divided into two categories: post-market surveillance (PMS) and vigilance. The first is a proactive measure that consists in the collection of data regarding the quality, safety and performance of medical devices once they have entered the market. Vigilance, on the other hand, is a reactive measure that consists in the report of incidents that may occur when medical devices do not perform as intended, leading to injury or, in the worst case, to death. With vigilance, one aims to protect the health and safety of both patients and healthcare professionals, evaluate incidents and avoid relapses, and learn from experience.
Post-market activities, besides being a regulatory obligation, are a good business practice because they help manufacturers to understand the performance of medical devices once they enter the market. Furthermore, they provide feedback that is essential to maintain quality and consumer satisfaction and allow the promptly deployment of warning and product recall procedures in case of incidents.
The requirements for PMS can be found in the European Unions' Medical Device Directives, the quality standards ISO 9001 and ISO 13485, and the risk management standard ISO 14971. This information can be

complemented by two guidelines published by the European Commission: MEDDEV 2.12-1 rev 6 from December 2009 and NB-MED/2.12/Rec1.

The responsibility over post-market surveillance lies over manufacturers as well as competent authorities, custom officials, notified bodies, authorized representatives, importers/distributers and users.

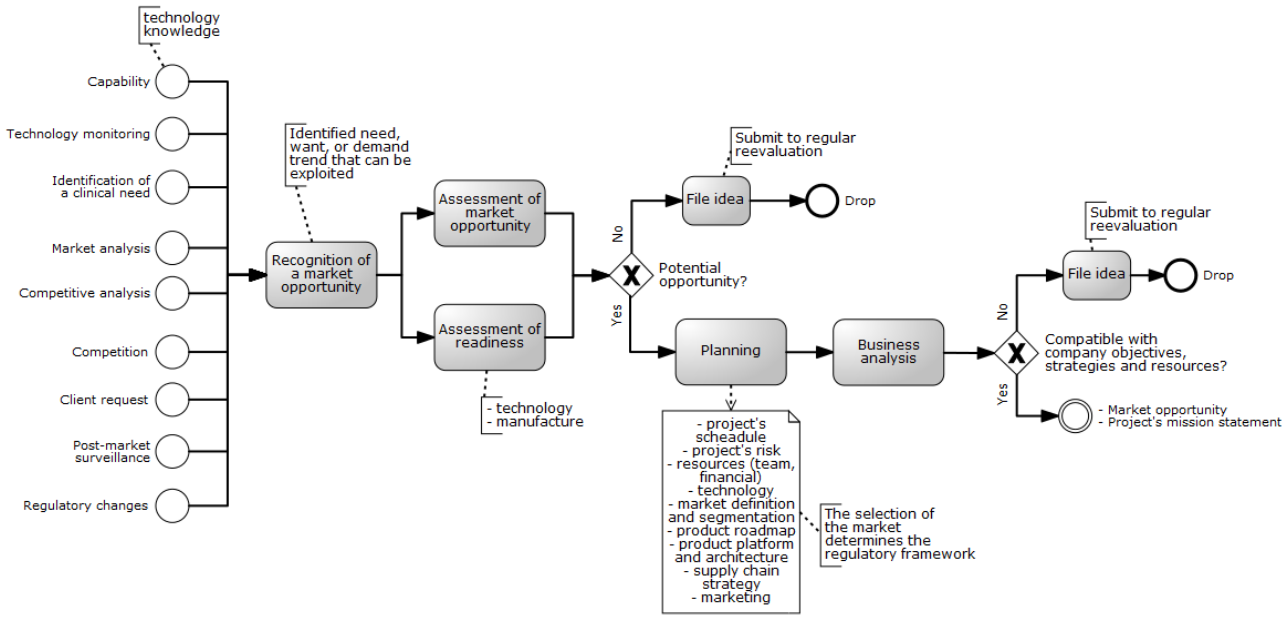

Figure 2: Idea creation process.

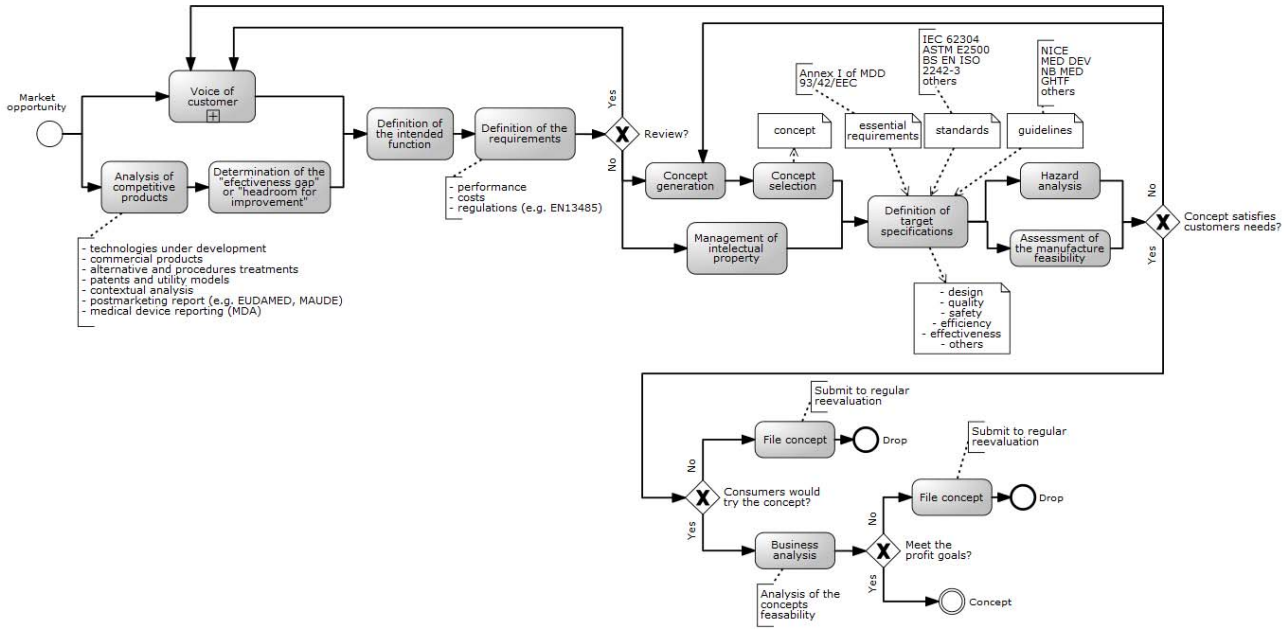

Figure 3: Concept development process.

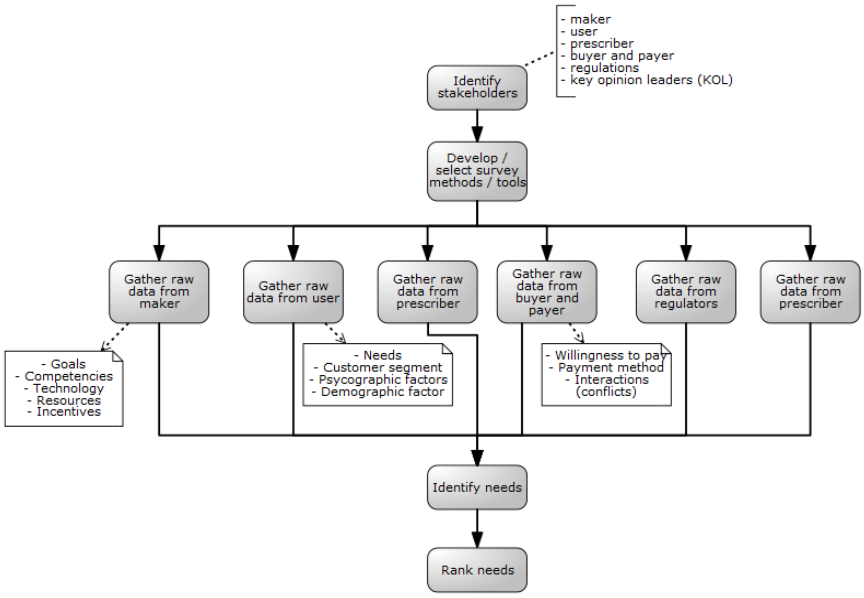

Figure 4: Voice of the customer process.

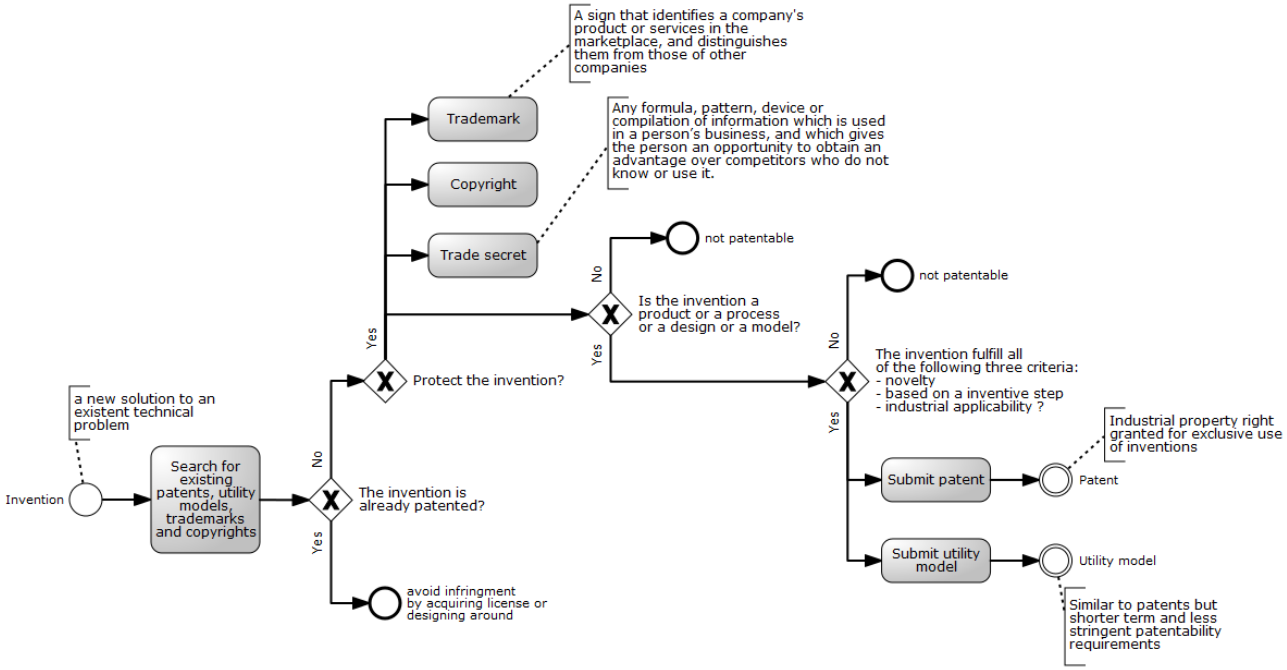

Figure 5: Management of the intellectual process.

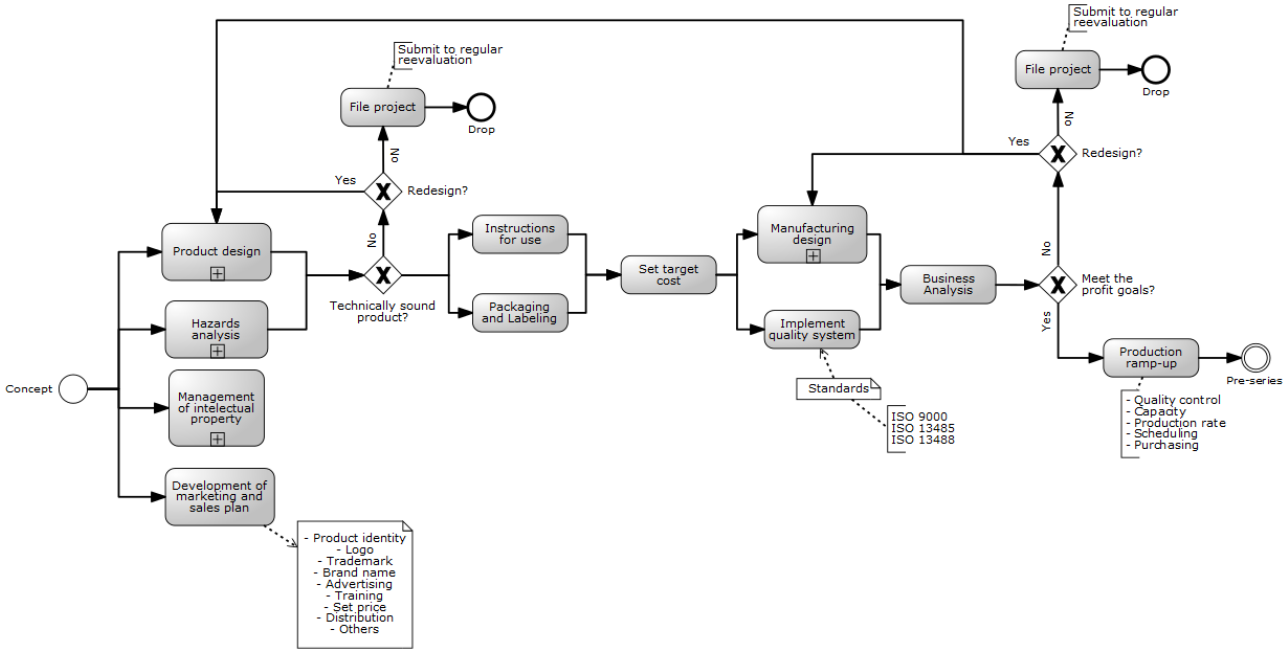

Figure 6: Design process.

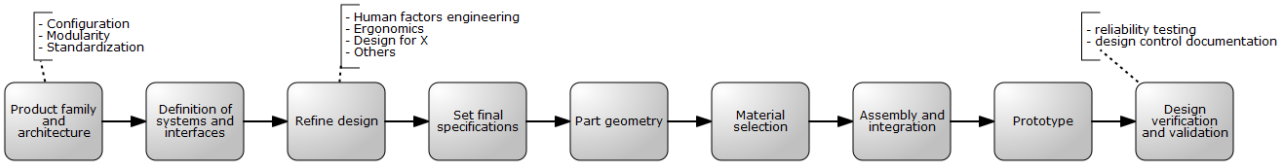

Figure 7: Product design.

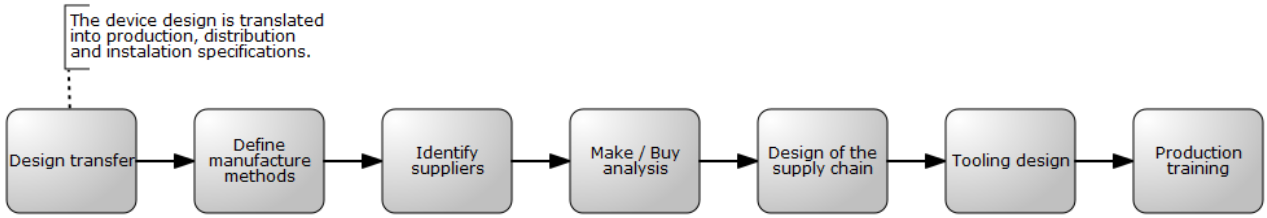

Figure 8: Manufacture design.

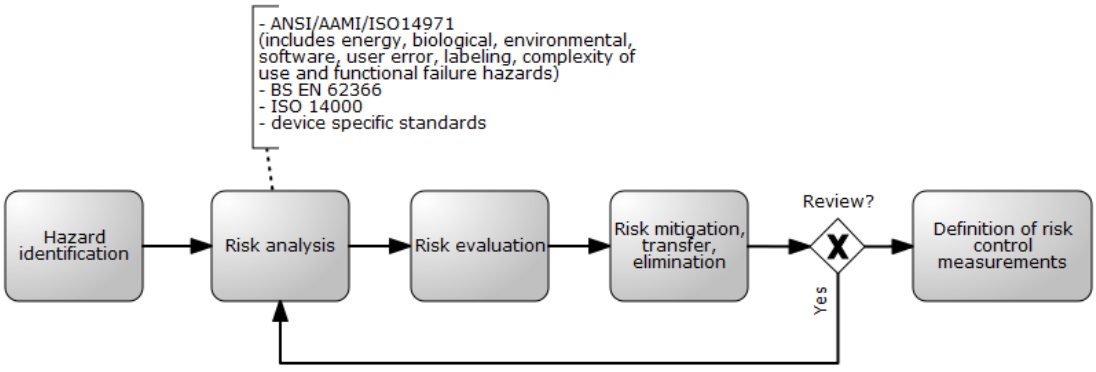

Figure 9: Hazard analysis process.

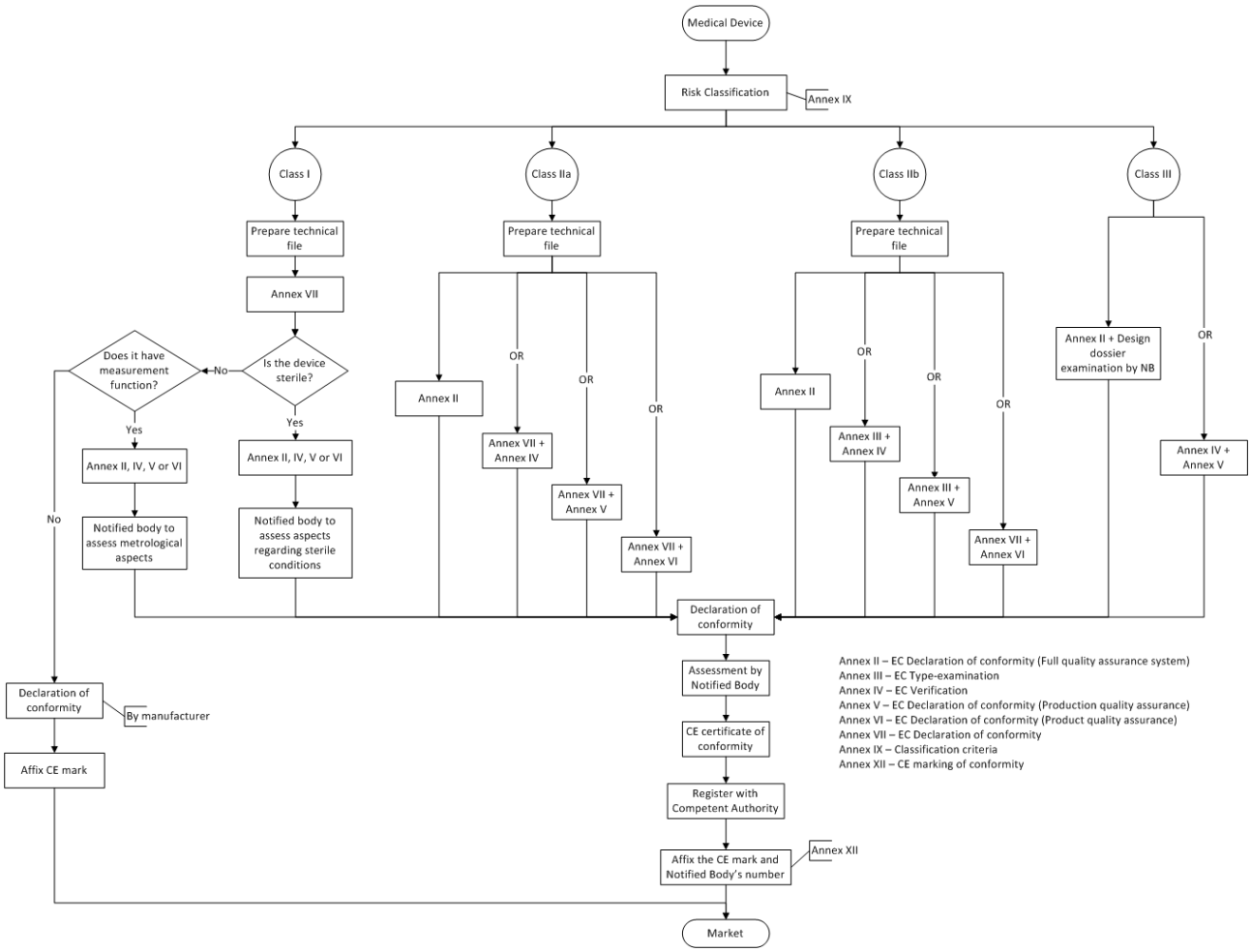

Figure 10: Flowchart with the European path to market.

5 CONCLUSIONS

In spite of the graphic representation of the product development process not being new, so far, there is not a representation specific to medical devices. These products justify such a representation because they have features that make them peculiar. In this paper, those features were presented together with a representation of the European environment in which medical devices are developed. In the future, it is relevant to repeat this exercise to the American market since it is the world's largest.

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REFERENCES

[1] Ulrich K., Eppinger S.: Product design and development. 5th ed. McGraw-Hill/Irwin, 2011.

[2] Sheridan N., Gustavson P., Smith K.: Product development as a competitive advantage. Engineering Management, 13(2):38-41, 2003.

[3] Owens J., Cooper R.: The importance of a structured new product development (NPD) process: a methodology. In: Engineering Education: Innovations in Teaching, Learning and Assessment (Ref. No. 2001/046), IEE International Symposium: 10/1-10/6, 2001.

[4] Brown A., Dixon D., Eatock J., Meenan B. J., Young T.: A survey of success factors in New Product Development in the medical devices industry. In: 2008 IEEE International Engineering Management Conference, 1-5, Jun. 2008.

[5] Shah S. G. S., Robinson I.: Medical device technologies: who is the user? International Journal of Healthcare Technology and Management, 9(2): 181-197, 2008.

[6] WHO: Medical device regulations: global overview and guiding principles. vol. 24, no. 3. Geneva: WHO, 2003.

[7] Altenstetter C.: EU and member state medical devices regulation. International Journal of Technology Assessment in Healthcare, 19(1):228-48, 2003.

[8] "National Innovation Centre." [Online]. Available: http://www.nic.nhs.uk/. [Accessed: 21-Sep-2011].

[9] Axendia Inc. & Cambashi Inc., Total Product Lifecycle Management : Lowering costs while Increasing quality, 1:1-36, 2009.
[10] Aitchison G., Hukins D., Parry J., Shepherd D., Trotman S.: A review of the design process for implantable orthopedic medical devices. The Open Biomedical Engineering Journal, 3:21-27, 2009.
[11] Aguwa C. C., Monplaisir L., Sylajakumari P. A., Muni R. K.: Integrated fuzzy-based modular architecture for medical device design and development. Journal of Medical Devices, 4(3): 1-10, 2010.
[12] Pietzsch J. B., Shluzas L. a, Paté-Cornell M. E., Yock P. G., Linehan J. H.: Stage-gate process for the development of medical devices. Journal of Medical Devices, 3(2):1-15, 2009.
[13] Das S. K., Almonor J. B.: A concurrent engineering approach for the development of medical devices. International Journal of Computer Integrated Manufacturing, 13(2):139–147, 2000.
[14] Alexander K., Clarkson P. J.: Good design practice for medical devices and equipment, Part I: A review of current literature. Journal of medical engineering technology, 24(1):5-13, 2000.
[15] Medina L. A., Wysk R. A., Kremer G. E. O.: A review of design for X methods for medical devices: The introduction of a design for FDA approach. In: Proceedings of the ASME 2011 International Design Engineering Technical Conferences & Computers and Information in Engineering Conference IDETC/CIE 2011, 2011.
[16] Briol P.: BPMN the business process modeling notation. 2008.