A dedicated methodology for the development of new medical technologies

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Abstract. The scientific discoveries of the last century are responsible for most of the medical devices currently in use. In this century, considering the advances namely in the computational power and the diffusion of the internet, one can expect a revolution in the use of medical technologies. Most certainly, new products and services will appear but only the ones that are supported by solid business plans will thrive. To assist in the development of novel medical devices and services and the elaboration of convincing business plans, the use of a product development methodology dedicated to medical technologies is suggested in this paper. Considering that many medical device companies spin-out from universities, this procedure aims to assist academia to cross the "valley of death", i.e., the chasm between the world of research and the world of trade and industry.

1. Introduction

Methodologies for the development of novel products can be understood as recipes to convert ideas or technologies into commercial products and services. Hardly, one can say that it is a simple and straightforward process but, for sure, the beginning is particularly hazy. In fact, some authors call this stage the "valley of death" as a metaphor to describe the insufficiency of resources and expertise in the area [1].

The entrance in the valley of death generally occurs when a working prototype is developed in academia for proof-of-concept but a commercial application is not foreseen. There are several explanations for this; for example, deficient protection of the intellectual property, high manufacturing costs, wrong audience, i.e., incorrect interpretation of the customer needs, and insufficient funds.

O'Brien et al. [2] adopted the perspective of both researchers and developers to describe multiple approaches to cross the valley of death. However, they have disregarded an important one: the adoption of structured methodologies. Here, we pretend to fill that gap by suggesting a product development methodology dedicated to medical technologies that can be used by academia, as well as industry, to transform proof-of-concepts, or just ideas, into successful commercial products or services.

Medical technologies were considered because, in the one hand, many companies related to medical device spin-out from universities and, on the other hand, this industry is described as dynamic and in continuous growth [3]. Nonetheless, the proposed methodology can be adapted and used in the development of other products.

2. Review of the methodologies concerning the development of medical technologies

Richard C. Fries has published several books and articles concerning the development process of medical devices [4], [5]. In his work, he gives particular attention to the legislation that medical devices must comply with and the development process is described as having multiple phases and involving the customer, the company, potential vendors and technologies. To gather information for each phase, several questions should be answered and, to integrate that information and also support decision, he suggests the use of quality function deployment (QFD), namely the house of quality (HoQ).

Aitchison et al. [6] divided the design process of implantable orthopedic medical devices into six areas: (1) market, (2) design specification, (3) concept design, (4) detail design, (5) manufacture and (6) sell. However, they proposed a more detailed structure and focused several aspects such as feasibility and design transfer.

Recognizing the crucial role of quality in the development and, predominantly, production of medical devices, El-Haik [7] presents the medical device's typical lifecycle and suggests tools that can be used in each stage. A similar work was presented by Gopalaswamy et al. [8].

Shah et al. [9] studied the relevance of user involvement in the development of medical devices; they divided the development process into 4 stages: 1 - idea generation & concept development; 2 - device (re-)design & prototype development; 3 - prototype testing in-house & trials in real field; 4 - device deployment in the market & user feedback; and, for each stage, proposed various tools to engage users in the process.

The authors presented thus far are vague in their description of what happens during each phase of the medical device development process. On the other hand, the work from Pietzsch et al. [10] and the textbook of the Stanford University [11] are more detailed. The former describes the medical device development process adopted by the USA's industry; it is similar to the stage-gate model and enumerates the multiple tasks that are performed, when they are conducted and by whom. The latter detailed each step of the process from needs finding and screening to business models and funding.

The work of Santos et al. [12] is also detailed; the authors depicted the multiple steps of the medical device development process in Europe using Business Process Model Notation (BPMN). In order to work as a constant reminder, they prepared a poster that should be hanged next to its readers. As tasks were not assigned to functional groups, the authors believe that academia will be open to the adoption of their methodology. However, further studies on this topic are required.

3. New methodology for the development of medical technologies

Santos et al. [12] studied the development process of medical devices in Europe. Here, that methodology is generalized so it can be used in other markets as well. Notice that, as medical devices range from tongue depressors to sophisticated lab-on-a-ship technology, the proposed methodology should not be seen as a rigid recipe; on the contrary, it should be used as a guidance document to which tasks are added or eliminated as needed.

Conceptually, the medical device development process is represented as a cycle divided into 6 stages: 1 - idea creation, 2 - concept development, 3 - design, 4 - medical device, 5 - regulatory approval and clearance, and 6 - post-market activities. The fourth stage "medical device" was included because in Europe both the device and its manufacturing process are subject to approval; that is, the approval and clearance process can only start when the device is being manufactured. As in other markets the approval process can start during the design phase, in the new version, the

"medical device" was represented as a slice "coming out" of the process (Fig. 1). Each stage depicted in Fig. 1 is composed by multiple tasks that are described next.

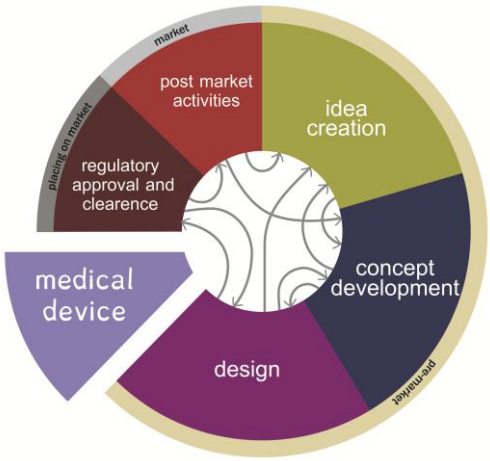

Fig. 1. New representation for the development process of medical devices.

3.1 Idea creation

In the development of novel products or services, the first step is the recognition of a market opportunity. This opportunity may appear from various sources, such as market analyses, client requests or the possibility to apply new technologies or knowledge, e.g., decoding the human genome allowed the appearance of gene therapy.

The next step is the assessment of the opportunity; one should question if the market is ready, if there is technology available, or it is possible to manufacture a solution at an affordable price. For example, ultrasound testing was invented in 1826, but only in the 1940s began being used in medical diagnosis.

After validating the market opportunity, it is necessary to select the countries where the novel device or service will be commercialized. This determines the regulatory frameworks that must be complied with and allows to define the reimbursement strategy which will impact the attainable revenues. Then, it is possible to plan the development process, namely the project's schedule and resources. At this point, it is advisable to conduct a business analysis to verify if the project meets the organization's goals.

3.2 Concept development

Having identified a market opportunity, the development of concepts can begin. This stage starts, in the one hand, with the identification of the customer's needs and, on the other hand, with the analysis of competitive products and the determination of the "headroom" for improvement; i.e., the maximum amount that a technology can be brought to market and still be considered cost-effective [13], [14].

The identification of the customer's needs, or voice of the customer, is a sub process in which the medical device users are identified (Fig. 2), the survey methods are designed, applied, and then the results are interpreted.

The listing of the most recent stage in the development of the product or service being designed, incorporating the newest ideas and features, is essential. Not only should the current commercial solutions be studied, but also patents, alternative treatments and new technologies. This information prevents that the design team conceives a product that is already in the market or protected by patents.

Knowing how much one can spend in the development of the novel device or service and what customers really want, it is possible to define the function and the requirements of the new device or service. Following, various concepts, i.e., possible solutions for the problem in hands, are generated and one is selected to be developed. During this phase, the management of the intellectual property is important to avoid patent infringements and protect novel ideas with patents, trademarks, copyrights

or trade secret. Furthermore, it can be a differentiation factor of the business plan for the new product or service. Researchers should also weight the academia's typical pressure to publish with the patent's requirement of novelty.

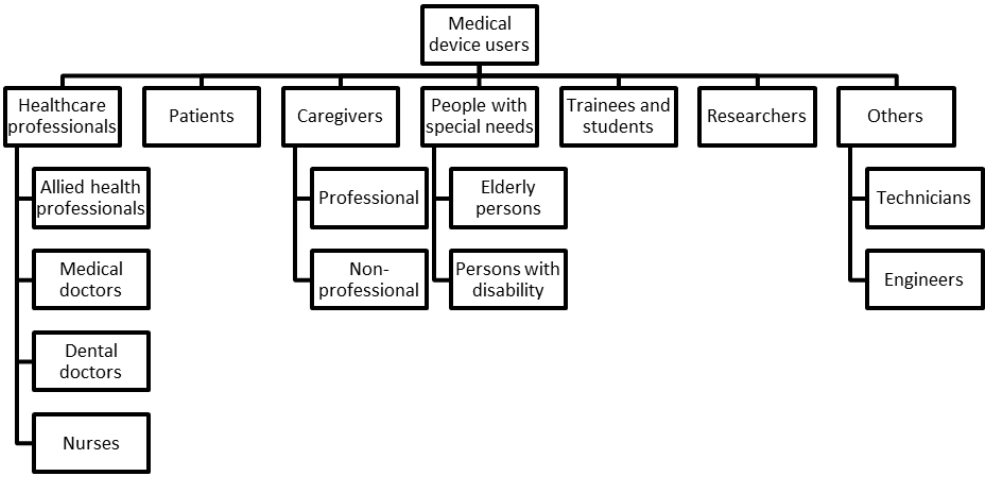

Fig. 2. Classification of users of medical devices.

In the definition of the target specifications, both standards and guidelines should be considered. This ensures that the product or service meets the requirements of the various regulatory frameworks; e.g., in the USA, the current good manufacturing practices or CGMP's.

The following steps are evaluative ones; it is necessary to assess if it is possible to materialize the selected concept, conduct hazard analysis and repeat the business analysis with the new information.

As far as the hazard analysis is concerned, it is a sub process that can be represented as shown in Fig. 3. It should be carried out several times along the development process. At this stage, it is desirable to eliminate the risks that the concept may pose and, if necessary, new concepts should be generated.

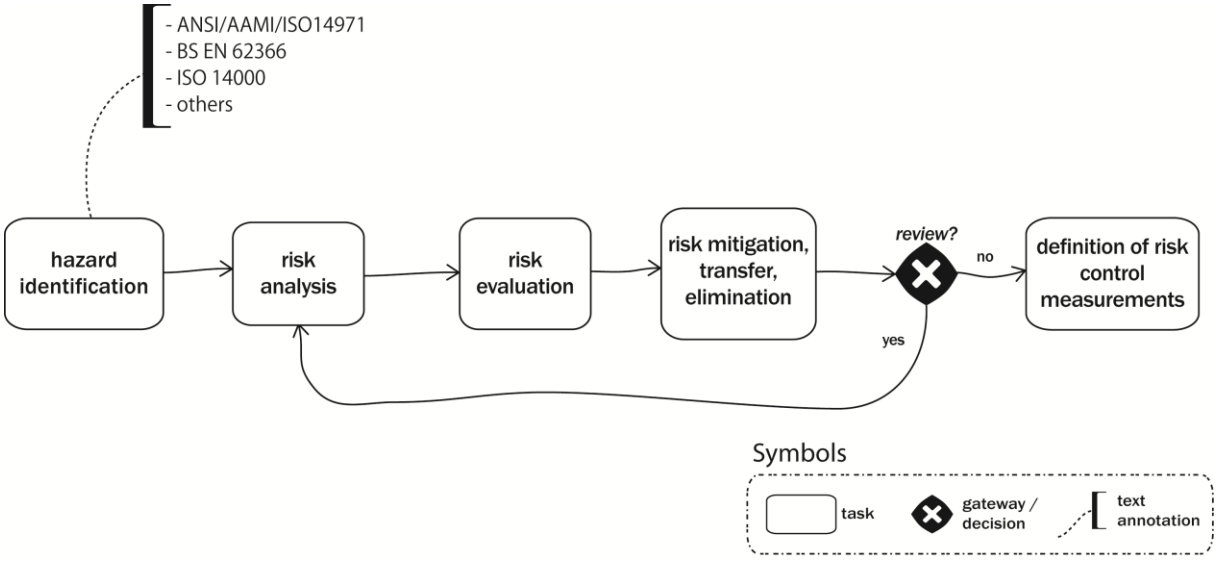

Fig. 3. Hazard analysis sub process,

3.3 Design

During the design stage, tasks can either be performed sequentially or concurrently. At this point, concepts are detailed and the final specifications are set; engineers define the product's geometry and select materials; prototypes are created, tested and validated. Hazard analyses are also conducted to

mitigate, or preferably, eliminate risks and prepare post-market surveillance. Manufacturing is addressed as well the instructions, packaging and labeling.

The information available at this time allows setting the target cost and preparing the marketing and sales plan, including the reimbursement strategy.

Considering the target market, the regulatory and clearance process can begin.

3.4 Regulatory approval and clearance

The regulatory and approval process differs from country to country. In the literature, there are several representations of the process, namely the one presented in the work of Santos et al. [3].

3.5 Post- market activities

Post-market activities either are proactive or reactive. Post-market surveillance (PMS) are proactive because consist in the collection of data regarding the quality, safety and performance of medical devices once they have entered the market. Vigilance is a reactive measure; it 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.

During the development of novel products or services, if a hazard analysis is conducted, the risk control measurements are defined.

4. Summary

The adoption of a structured product development methodology can be an effective solution to cross the valley of death. Here, a methodology dedicated to medical technologies was presented.

The proposed procedure aims to be a guidance document for both academia and industry. However, the robustness and versatility of the methodology described needs to be verified.

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