RISK ASPECTS AND MEDICAL DEVICE DEVELOPMENT PROCESS

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Abstract - Medical devices aim to monitor, replace or modify physiological processes and thus contribute to the maintenance and/or improvement of quality of life. However, the development of a new medical device is often uncertain and quite expensive. Therefore, designers and developers of a new medical device try to detect the risks, which each phase of medical device development process may encounter.The purpose of this article is to detect and discuss the risks and their sources, as well as their mitigation during the MDD process. This was done by a literature review of available sources found on the research topic in Web of Science and Scopus.The findings show the main risks during the MDD process together with their sources and their management. They reveal that the detection of risks and their sources in the MDD process plays a significant role since it can prevent a lot of adverse effects on the use of medical devices by the end users, save a lot of time on medical device design and development, as well as to reduce costs during the whole MDD process.

Index Terms - Identification, medical device development, risks, sources.

I. INTRODUCTION

As research shows [1], [2], medical devices significantly contribute to the enhancement of healthcare practices. They aim to monitor, replace or modify physiological processes and thus contribute to the maintenance and/or improvement of quality of life [3]. However, the development of a new medical device is often uncertain and quite expensive [1]. Moreover, due to the innovation research, medical device development (MDD) introduces a risk to the end-users [4]. In addition, there is a threat of business risks due to strict regulatory processes and potential litigations [1].Therefore, designers and developers of a new medical device try to detect the risks, which each phase of medical device development process may encounter. The most common used medical device development process seems to be a linear stage-gate process. The stage-gate system divides the innovation process into a predetermined set of stages, separated by gates characterized by a set of criteria to be met before the product can advance in the process. Each stage, in turn, is composed of a number of prescribed activities that are in many cases related and that can occur in parallel. The stage-gate proces consists of five key phases that are illustrated in Fig. 1 below.



Fig. 1. Phases of medical device development, adjusted according to [1]

Phase 1 usually includes a financial review, market analysis, legal analysis, regulatory review, and reimbursement strategy. In the end, a business plan is drafted. In Phase 2, a cross-functional team is set up in order to formulate concept and assess the device feasibility and develop a design plan.In Phase 3, a verification and validation test matrix is created by cross-functional team members.In Phase 4, formal design prints are made, consisting of both component and assembly-level drawings. Material specifications, packaging drawings, and marking and labeling specifications are also finalized in this phase, as well as the final verification and validation phase of device development.The key step in this phase in the USA is also to receive regulatory approval/clearance by the Food and Drug Administration.Phase 5 focuses on the product launch and post-market surveillance [2].
The individual MDD phases are closely connected with risks that the individual steps of MDD process cause. Thus, the purpose of this article is to detect and discuss the risks and their sources, as well as their mitigation during the MDD process.

II. METHODS

The methods are based on a literature review of available sources found on the research topic in Web of Science and Scopus. The searched keyword collocations were medical devices AND development AND process AND risks. In addition, websites on the MDD and riskswere also checked, for example, Med Device Online [5]. The search was not limited by any period because there were not many findings on the research topic.The study was included if it focused on the research topic, i.e. risks and their sources in MDD process and if it was a reviewed full-text English written study. Thus, both original and review studies were included. In addition, references of the selected articles were then carefully checked to avoid a

possibility of leaving out an important study on the research topic. Eventually, the author used 12 sources, which are listed in the section on References.
The author also used methods of comparison and evaluation of the findings from the selected relevant studies.

III. FINDINGS AND DISCUSSION

The findings show that there are not many studies on the identification of risks in the MDD process. The most representative and detailed study is by Kirkire et al. [4].These researchers divide the sources of risks into three groups. They are as follows:
1. Internal sources of risks which appear due to operating strategy of the companies and are mostly associated with structure and culture of the company.
2. User related sources of risks connected with various adverse causes to users.
3. Third party related sources of risks which are associated with different third parties such as regulators, buyers, and even users.
Fig. 2 below then provides a detailed classification of these three groups.

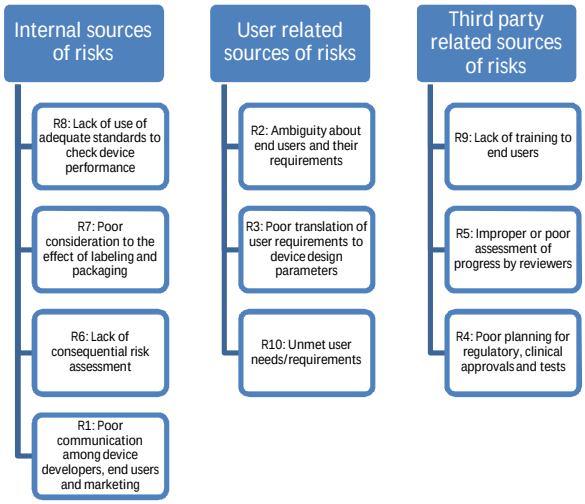


Fig. 2. Classification of sources of risks

The authors evaluated and ranked these sources of risks with the help of the Framework of Technique for Order Performance by Similarity to Ideal Solution (FTOPSIS) and sensitivity analysis. Their findings indicate that the most important source of risks is unmet user needs, which means that user needs should be met in order to successfully market the device. This finding has been also confirmed by other research studies[6], [7], [8], [9], which claim that significant attention should be paid to human factors and usability in the MDD process.The second important source of risks then appears to be the effect of labelling and packaging and the third is poor communication among device developers, end users and marketing people.
For instance, van Kuijk [7] reports that there is a lack of user-centered design skills in device development teams or their late involvement, time and budget limitations, no communication with the end-users on a regular basis, insufficient communication with the team members and low awareness of the significance of usability in the project or organization.

Based on expertise, Peijl et al. [6] suggest implementing a sound, iterative usability engineering process into a regular, linear stage-gate process. They state that multiple iterations of the basic user-centered design cycle should be conducted in each MDD stage. These iterations consist of five main steps: analysis, definition of design criteria, synthesis of ideas, simulation and evaluation, a decision on how to proceed with results. The whole process should be planned and managed by a specialist usability engineer and the top management should provide enough time and relevant budget, ensure support from other disciplines and provide sufficient access to the end users.
Kirkire et al. [4]set several recommendations or measures, which should diminish the sources of risks. They are as follows:

- to develop strong marketing team which would constantly cooperate with the end users,
- to clearly identify all potential users of medical devices,
- to specify users' roles during each medical development stage,
- to perform independent reviews together with team reviews,
- to include clinicians into each phase of MDD,
- to design device with complete, clear and constant user expectations in mind,
- to develop internal risk management expertise,
- to incorporate quality management systems (ISO 13485) and risk management system (ISO 14971) which will consider regulatory requirements and risk assessment,
- to raise use of risk management techniques, e.g., preliminary hazard analysis or fault tree analysis,
- to maintain and periodically update design history file,
- to conduct the risk-benefit analysis,
- to avoid underestimation of technical failures,
- to include doctors in MDD processes to avoid negative aspects,
- to prefer independent reviews to avoid bias in assessment due to group reviews,
- to perform risk assessment of labelling and packaging,
- to conduct periodical training to all stakeholders.

All these aspects can help reduce failures of MDD processes.

Furthermore, Kirkire et al. [8] also provide specification of activities and their risks in each phase of MDD process. Consult Table 1 below.

Table 1. Specifications of activities and their risks in MDD process

Phase	Activities	Risks
Concept	• capturing customer requirements • finding alternative concepts, • screening for regulatory strategy • screening for tooling and fixtures	• ambiguity in capturing the customer requirements • lack of modeling the captured requirements • poor evaluation of the requirements in detail • poor evaluation
Architecture	• formation of core team • preparing time schedule • supplier selection and planning • preparing validation plan	• lack of decomposition of the tasks involved • poor selection of methods to accomplish the tasks • mapping of available resources with the required • poor selection of team members
Development	• deciding design inputs • planning for manufacturing • regulatory strategy • clinical validation studies • preparing prototypes	• poor design specifications • lack of planning for manufacturing resources • poor quality requirements definition • poor validation strategies
Testing	• prototype evaluation • product risk analysis • finalizing process parameters • continued clinical testing	• wrong selection of design performance parameters • poor risk management plans • discontinued clinical testing • lack of process qualification criteria
Validation and launch	• validation of product • product launching • training to dentist/users • feedback for improvement • quality audits • continued clinical validation	• poor product branding and launching strategy • lack of continuous training to product users • lack of post-launch quality audits • Discontinued clinical validation

Another detection and mitigation of risks in the MDD process was conducted by McPhilliamy [10] who demonstrated this process with infographic (Fig. 3).

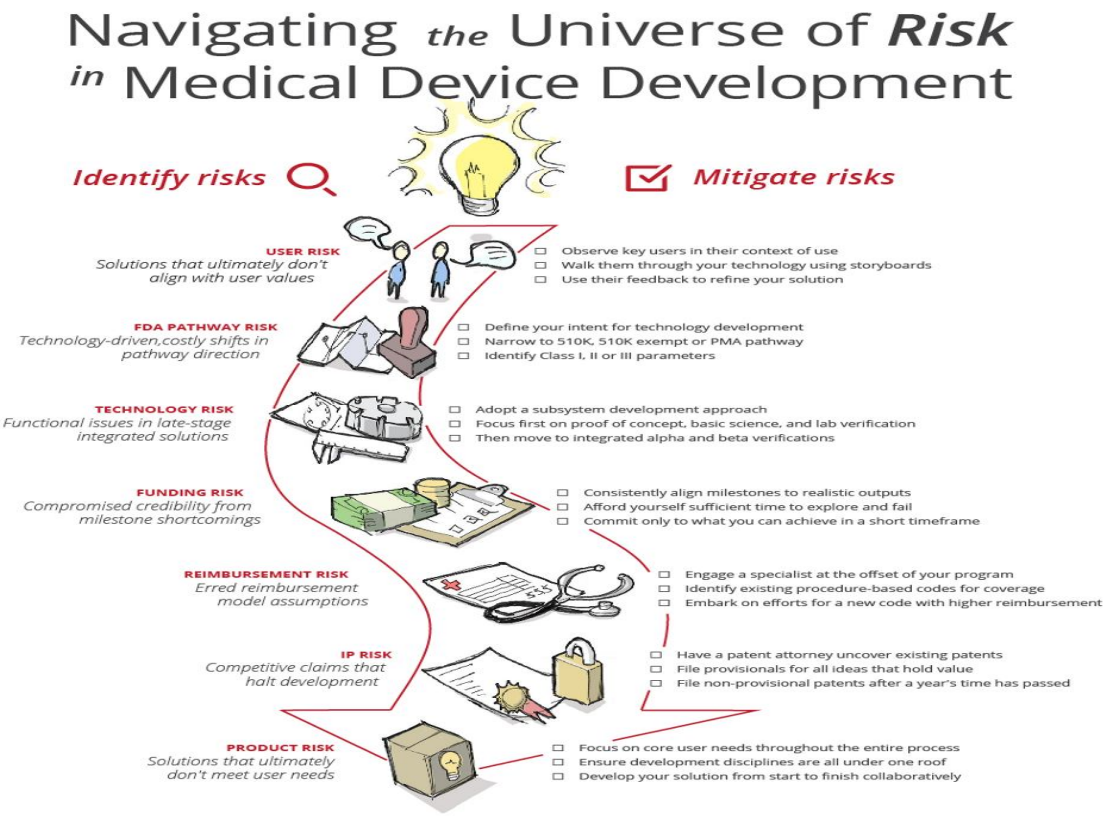


Fig. 3. Process of the risk detection and mitigation in MDD [10]

During initial stages of MDD, the risks are less severe but as the process progresses, the severity of risks increases [8].For example, Aguwa et al. [11]present that medical devices incur high (90%) failure rate during the first prototype test.Therefore, Kirkire et al. [8] proposed MDD process risk mitigation model which is illustrated by Fig. 4 below.

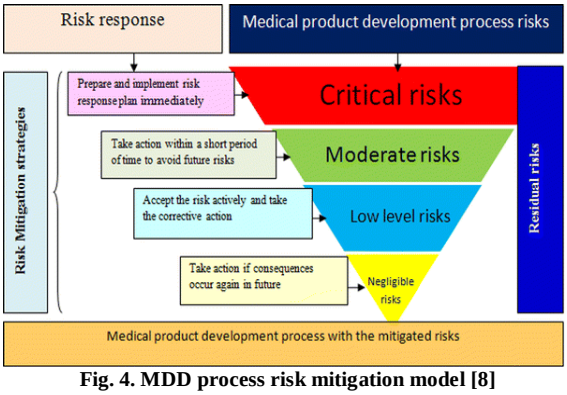


Fig. 4. MDD process risk mitigation model [8]

Finally, all these risks are analyzed, evaluated and monitored by a thorough risk management lifecycle, which consists of five standard steps [12]:

1. Risk management framework and planning (Risk management must be defined with respect to the regulations of FDA or ISO, as well as risk management plan has to be created).
2. Risk analysis (During this phase, the foreseeable hazards needs to be identified.)
3. Risk evaluation (In this phase, severity and occurrence/probability of risks are identified, as well as proper visualization of the risk on a matrix is performed.)
4. Risk control (The implementation of risk mitigation is conducted.)
5. Reports and documents (The risk management plan and strategies are documented.)

CONCLUSION

The findings show the main risks during the MDD process together with their sources and their management. They revealthat the detection of risks and their sources in the MDD process plays a significant role since it can prevent a lot of adverse effects on the use of medical devices by the end users, save a lot of time on medical device design and development, as well as to reduce costs during the whole MDD process. Therefore, the MDD process should be critically designed and simulated to minimize the number of risk events and their severity [8].

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