Integrating a Usability Engineering Process into a Consisting Risk Management

Abstract: The complexity of medical devices and its user interactions increases. A growing number of incident reports are assumed to be associated primarily with user errors. This development is tackled through current modifications in standards, such as ISO 13485:2016 and legislations, such as the Medical Device Regulation. Both intensify the focus on use errors significantly. The aim of this paper was the development of a process orientated approach integrating usability engineering into a consisting risk management based on a classic V-model. An appropriate procedure was worked out. For each development step, risk and usability activities were cumulated. Thus, the present paper might help medical device manufacturers to reflect their risk management and usability management processes to find synergies. Prospectively, a step-by-step guide for the integration of risk management and usability engineering based on this approach should be developed.

Keywords: Risk Management, Usability, Regulatory Affairs

1 Introduction

Each year, the U.S. Food & Drug Administration (FDA) receives approximately 100,000 incident reports for medical devices. About one third of these reports are assumed to be associated primarily with user errors [1]. This number corresponds with data analysis on medical device recalls between 2003 and 2012, published by FDA [2]. A retrospective study regarding 1,222 incident reports collected by the German Federal Institute for Drugs and Medical Devices (BfArM) states that 42.1 % of the reports were attributed to use errors [3]. Also, a study by Walsh et al. [4] shows that about 87 % of all incidents in medical environments, where patient monitoring takes place, are caused by usability issues.

Thus, it is not surprising, that the new revision of the ISO 13485 (Medical devices – Quality management systems – Requirements for regulatory purposes) underlines both, risk management and usability engineering [5]. A usability engineering process can reduce use errors and increase safety education of use errors, which are only two aspects among others, e.g. it facilitates recovery from use error, decreases training time, increases ease of use, facilitates the regulatory approval process and increases the chance of commercial success [6].

The usability engineering and the risk management processes belong together. Therefore, an incorporation of usability aspects into risk management will help to identify, describe and mitigate hazards that are caused by usage [7]. More precisely, the standards and guidance documents regulating the usability engineering process in the field of medical devices [8,9] directly focus on identifying and mitigating risks by means of use scenarios [10]. In contrast, traditional approaches of usability engineering also focus attributes as time to learn, speed of performance and satisfaction [11].

The aim of this paper is the development of a process orientated approach to integrate usability engineering into a consisting risk management. The developed process should be based on a classic V-model to allow an easy transfer to most development processes. The main idea of simplification is to find synergies between usability and risk management to reduce work steps.

2 Material and Method

Based on a literature research, all relevant European standards and guidelines were sighted. Usability and risk management aspects were worked out to develop an integrative process workflow. Comparisons with other examples (such as the FDA model) were made. The following literature was used, and relevant information was extracted and condensed:

- Directives (EU) 93/42/EEC and 2007/47/EC
• Regulation (EU) 2017/745
• EN 14971 and EN 62366
• Applying human factors and usability engineering to medical devices (FDA Guideline)

3 Results

Based on relevant literature and guidelines, a process orientated approach for the integration of a usability engineering in a consisting risk management was developed. Figure 1 shows the rough sequence, the more detailed procedure is explained in the following. Therefore, the demands from EN 14971 and EN 62366 are matched to the corresponding design development steps:

Design Input
• Application specification is part of intended use.
• Frequently used functions are those referring to the device user interface.
• To identify characteristics related to safety, known and foreseeable hazards and hazardous situations, we suggest the risk management technique Preliminary Hazard Analysis (PHA).
• PHA is a method that is used early in the development process. It can be useful when there is little information on design details.

Design Specification
• To investigate adequate mitigations measures for the identified hazards, the Fault Tree Analysis (FTA) is suggested. PHA results can be used as FTA top event.
• The application specification, the primary operating functions and the determined mitigation measures are input to generate the usability specification.
• The usability specification should include the definition of use cases.
• The validation plan contains acceptance criteria for validating the usability of the primary operating functions. The frequent use cases and worst use cases should be considered.

Development and Test
• The user device interface is designed and developed according to the usability specification.
• The development is an iterative process where the user should be involved.
• During the development process the Design Failure Mode and Effects Analysis (D-FMEA) should be applied.

Industrialization
• The implemented user device interface is tested to verify the usability specification.

![Diagram of the process]

Figure 1: Risk and usability activities are assigned to the typical stages of a development process according to classic V-model.
• In case of resulting usability design modifications, the D-FMEA must be updated.

Launch
• In accordance with the validation plan usability tests are performed.
• The standard EN 62366 requires the conduction of the tests with the intended (actual) users in a simulated or in the real use environment. The test scope must be risk-based, so all critical tasks are covered. The FDA Guidance “Applying Human Factors and Usability Engineering to Medical Device” provides a more detailed instruction for usability validation in chapter eight.

4 Discussion

The developed process orientated approach represents an easy way to integrate a usability engineering process into a consisting risk management, regarding the relevant guidelines and regulation. Risk management activities are conducted including the demands from the usability engineering process to achieve an efficient integrated procedure.

This is important for medical device manufacturers because the new Medical Device Regulation [12] intensifies the focus on use errors, outlined in the following chapters:
• Appendix I (I) 5.: “In eliminating or reducing risks related to use error, the manufacturer shall:...”
• Appendix I (II) 14.6.: “Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles,...”
• Appendix I (II) 22.2.: “Devices for use by lay persons shall be:...”
• Appendix I (II) 22.3.: “Devices for use by lay persons shall,...”
• Appendix I (III): „Requirements regarding the information supplied with the device“
• Appendix II 6.: „Product verification and validation“

Thus, the present paper might help medical device manufacturers to reflect their risk management and usability management processes to find synergies. For each development step, manufacturers can rely on this developed approach.

Nevertheless, this approach needs further fine tuning and feedback from manufacturers. Prospectively, a step-by-step guide for the integration of risk management and usability engineering based on this approach should be developed.

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References