BOOK CHAPTER | Medical Device Development
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Relevance of Requirement Engineering In Medical Devices Development

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ABSTRACT

Medical device development life cycle requires the strict adherence to the stages outlined by the regulatory bodies to ensure safety of use by patients and clinicians and to ensure high quality products. This chapter tactfully describes how introducing the process of requirement engineering into the medical device development procedures can help in creating high standard medical devices to improve health care administration.

Keywords: Medical Devices, Patients, Clinician, Requirement Engineering, Health Care, Safety.

Introduction:

Medical devices can be described as instruments, equipment, machines implants, software and/or related or similar articles which the developer intends to be used for medical purpose.

The process of development of medical devices entails the use of specific stages to ensure the attainment of appropriate design control for product safety and efficiency. According to Quasar (2019), the regulatory body for standardization of medical devices in the United States which is the Food and Drug Administration (FDA) outlined the major stages for medical devices development which form their quality system regulation (QSR). This governs the techniques used, the facilities, as well as the all the facilities and controls used for the design, development, packaging, labelling, storage and servicing of finished medical devices.

The FDA Stages For Medical Device Development

The FDA stages for medical device development include:

a. The risk analysis stage/initiation
b. The concept formulation and feasibility analysis stage
c. The design and development stage which also include validation and verification of design
d. The product launch preparation and post launch assessment
e. And last validation.

Medical Devices Classification

Medical devices are also classified into three classes based on their risks and the regulatory controls necessary to provide assurance of safety and effectiveness into class 1, 11, or 111. (www.fda.gov)

Class 1 include devices with the lowest risk, class11 are those devices with moderate risk while class 111 include devices with the greatest risk.

Medical Devices & requirement Engineering

In order to successfully develop quality devices that will meet approved standards, a collaboration of many persons in the various engineering disciplines are required to work as a team. Hence the need for a critical process to help the team manage the complex requirements involved in the development life cycle of medical devices as well as to enhance the team's communication to produce a safe and effective product. This can only be achieved by employing requirement engineering (RE).

Jin (2018), described RE as the process of eliciting the needs and desires of stakeholders as well as developing them into a set of detailed requirements which can serve as a basis for all subsequent development. Requirement Engineering entails the process of designing, documenting, establishing and managing requirements. It is a critical process that consist of requirement discovery and elicitation, specification, analysis, verification and management. (Boulanger, J., 2016). Requirement Engineering employs the up-front requirement definition and requirement management strategies to assist medical device developers to come to terms on the type of product they intend to develop.

The requirement definition stage describes the identification and discovery of the device of intent, the analysis, specification and possible verifications needed for the device. Requirement management helps to build the team cooperation and intercommunication within the team of manufacturers and stakeholders. It also will help to assess the outcome of any intended changes to be made. Requirement management helps to ascertain the different requirements per person downstream work product. It helps to determine the requirement of the device during development in order to keep proper surveillance of the status of the device development process. This will show the amount of requirement that have been used, the amount of requirement to be used and the amount not fully been used. Requirement Engineering enables medical device developers to ensure that whatever devices they are developing must match the project type.

Requirement engineering helps manufacturers to determine the requirements of the consumers of their products which must meet the requirements of the regulatory bodies prior and during device development to prevent failure during use. This will also help to prevent the development of substandard devices that will not meet patients or clinician's safety standards thereby risking the lives of the end users of the device.

Requirement Engineering and Software for medical Devices

Requirement engineering can produce software which is able to handle the major complexities involved in developing high-tech medical devices. Employing requirement engineering management software such as Rational DOORS assists

the team of engineers to work as a close unit and work towards understanding the needs of the end users as well as the basic regulatory requirement. (IBM corporation ,2009). This will in turn assist the developer to handle changes with strict accuracy and traceability. This capability helps to ensure that critical features are not omitted. Using requirement engineering enables distributed engineering team members to work together bearing in mind the regulatory guidelines.

This is capable of saving the organization from product recalls which may be so costly (Nuseibeh and Easterbrook, 2003). By using requirement engineering, medical device developers can save time, reduce cost and enhance user satisfaction for both patients and health professionals. Requirement engineering can also help medical device developers produce high quality devices. Conclusively, medical device development is a complex process with varying guidelines. By employing requirement engineering, high quality design and products are assured. The application of Rational DOORS requirement software developers can test each requirement to validate the efficiency of performance of their product.

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