Introduction to System Risk in Medical Device Design

Abstract:
Medical devices designed for human use can be used for diagnosis. Researchers are tasked with completing some of the more difficult tasks involved in making a medical device fit for human use. This means that the device should be safe, accurate, and cost-effective in terms of risk management, which entails identifying, understanding, controlling, and preventing failures that result in hazardous exposures while humans use medical devices.Risk and hazard analysis is a structured approach for assessing the potential difficulties that could arise from the usage of a medicine or a medical device.The purpose of this paper is to examine the necessity of risk analysis, risk management tools, and the risk management process's benefits. The ultimate goal is to reduce use-related risks, ensure that intended users can safely and effectively utilize medical devices throughout the product life cycle, and simplify the assessment of new device submissions and design control documents.

Keywords: Risk Analysis, Medical Device, ISO 14971, Risk Management

1. INTRODUCTION:

The globalization of the medical device industry, combined with the increased use of medical devices, has resulted in a major increase in the complexity of the process of developing a safe medical device among device producers. Risk management has evolved into a critical competitive strategy for gaining access to international markets[1,2,3,4]. The significance of adequate translation and safety controls will grow as clinicians, patients, regulators, and litigators become increasingly sensitive to various safety risks connected to human factors. Risk management is required to assure device usability, safety, and regulatory compliance; yet, in certain circumstances, crucial human factors and risk management choices are influenced by the language used in the user interface or labelling.[5,6] For example, dangerous circumstances might emerge if date/time information or units of measurement provided are incorrectly interpreted. The

impact of localization on these kinds of items is often not as carefully identified, controlled, verified, and validated during initial device development for the initial locale (e.g., the United States); however, mitigation of those risks is typically a key focus during initial device development for the initial locale (e.g., the United States); however, the impact of localization on these kinds of items is often not as carefully identified, controlled, verified, and validated during initial device development for the initial locale (e.g., the USA). The FDA's quality system regulation aims to provide producers with "the liberty to choose the controls that are necessary to be commensurate with risk."

The FDA considers risk analysis to be a legal necessity, but it can only provide limited recommendations on risk analysis methodologies and processes such as fault tree analysis (FTA) or failure mode and effects analysiS(FMEA). A medical device firm may find benefit in what other sectors, such as chemical, aircraft, and defences, have learned about utilising risk analysis to decrease risk after reviewing and updating numerous methodologies in risk analysis. Companies may better manage and decrease risk by incorporating risk thinking into device or process development as early as feasible and reviewing those problems consistently throughout the development process[7,8].

2. METHODOLOGY USED FOR RISK MANAGEMENT

FMEA is the risk management approach utilized in this study, through which the risks are identified and studied for their impact, and controls are implemented and monitored. Many standard reference papers are utilized in the medical device industry to identify the risks that exist throughout the life cycle of the device, whether it is during manufacture or post-production. The following are a few standard texts whose technique is utilized to detect risk in this study. Throughout the lifespan of a medical device, the FMEA (Failure Mode Effect Analysis) technique is utilized to mitigate all risks by implementing different risk controls. All related hazards are either lowered to an acceptable level or transferred by bringing in a third party for that specific equipment. [2,3].

Device-related risks must be identified and recorded using the standards outlined:

1. EN ISO 14971:2019, Medical Devices- Application of Risk Management to Medical Devices,
2. MDD 93/42/EEC amended by 2007/47/EC
3. EU MDR 2017/745
4. IEC 62366-1:2015, Medical devices- Part 1: Application of usability engineering to medical devices.
5. Device Design and Quality Management System

3. Risk management overview

Risk management essentially becomes an endeavor to control those uncertainties as it focuses on detecting, measuring, and characterizing uncertainties with losses. Risk managers use a variety of formal approaches, methodologies, and tools, including as trade-off analysis, cost-benefit analysis, risk effectiveness, and multi-attribute decision analysis, among others[6,7].

Risk management is the most essential and complex aspect of risk analysis, since it encompasses a wide range of disciplines ranging from subject matter specialists to risk and decision analysis. Even in the face of potentially risky systems and technologies, a competent risk management effort maybe very difficult to avoid, control, and minimize the loss. When humans utilize medical equipment, risk management focuses on identifying, understanding, controlling, and preventing malfunctions that might result in risks.All probable dangers that exist in both normal and fault conditions must be identified and calculated by a manufacturing business. If a risk is deemed intolerable, it must be minimized to a manageable level using approved methods[8,9,10].Figure.1 shows the risk management process in Medical Device chart for system risk Industry.

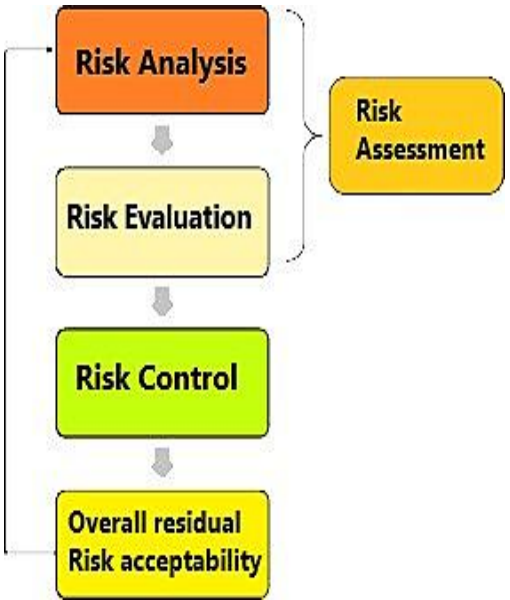

Fig.1 Risk management Process chart for system risk in Medical Device Industry

4. Risk assessment process in system

The risk assessment process that can be easily used here, risk (R) = severity (S) * Occurrence (O) identify specific hazards and assign them a value for each element below; the higher the number, the greater the severity and probability of occurrence of any risk[11,12]. Risk zones and Risk zones as per the acceptability are shown below in Figure. 2 and Figure 3.

4.1 Severity

The severity of the most likely result of a given hazard occurrence is represented on the risk matrix by severity. In other words, what is the severity of the most likely problem that will occur if a hazard arises and is not mitigated

i. Negligible
ii. Marginal
iii. Critical
iv. Serious
v. Catastrophic.

4.2 Probability of Occurrence

The likelihood that given the exposure, the projected consequences will occur. training, situational awareness and morale are used to mitigate probability. The probability of Occurrence is classified into five different levels in our organization as we are using 5*5 matrix. The probability of occurrence can be minimized by improving our industry internal quality and system. If the Occurrence is reduced to negligible then the risk consequences will directly mitigated to its lower occurrence level.

i. Negligible/ Improbable
ii. Remote
iii. Occasional
iv. Probable
v. Frequent

Finally, calculate the value of Risk (R = S × O) to evaluate the risk.

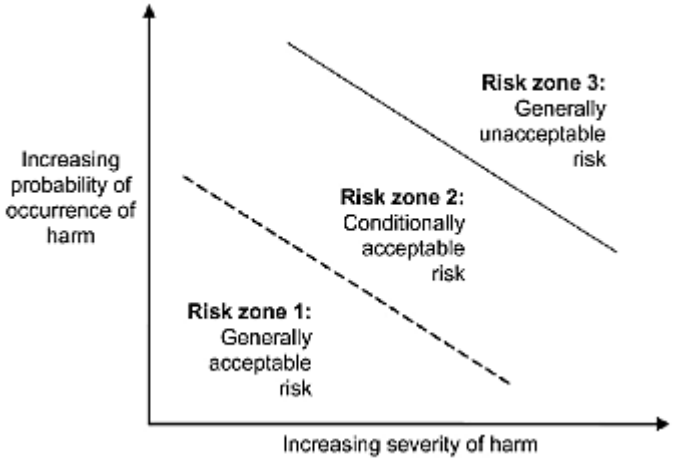

Fig.2 Figure representing the Risk Zones

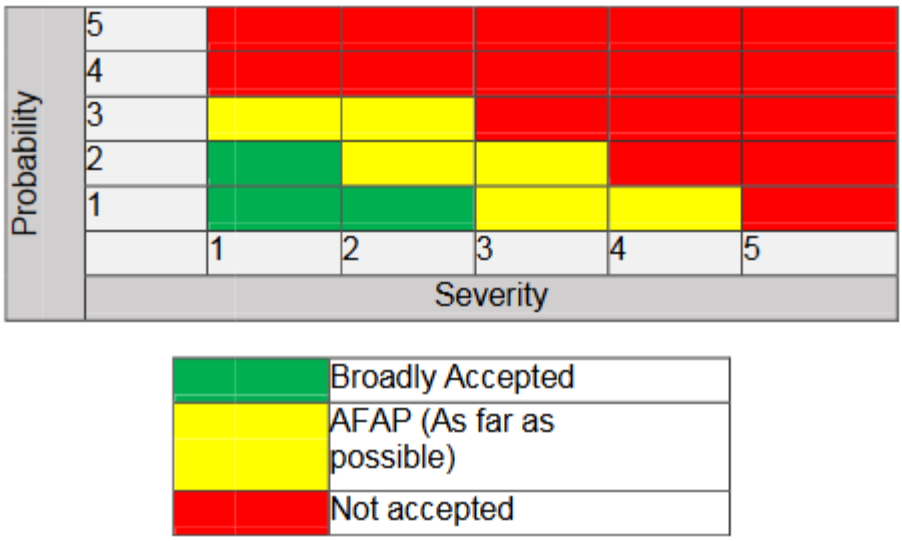

Fig.3 Risk Zones as per the acceptability

Conclusion:

The subjects covered have been utilized in the design and development of medical devices. FMEA is a major technique for risk analysis, thus there are several additional computer-controlled medical devices that need to be reviewed. FMEA is an excellent alternative for medical devices that aren't utilized with plasma or blood, as well as several other intravenous solutions. The key to a good medical device design is to get started as soon as possible.A hazard analysis can be helpful in determining the idea of the highest inherent safety.However, once the design development process begins, it will be possible to make essential adjustments without disrupting the project timetable.Changes that are discovered later in the design phase have fewer options for mitigating hazards without having a substantial impact on the timetable.Risk management initiatives will identify areas where device performance may be improved. The advantages of performing medical device design in risk management are substantial, but there is always a trade-off in risk management.

Hardware-software has been shown to be more trustworthy than people and to be more effective.However, because all medical devices require human involvement to function, the element of risk must be appropriately assessed.Reducing the amount of routine human involvement lowers risk and

increases efficiency.The expense of automating operations that can be handled by persons must be evaluated against the risk reduction.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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