

Introduction to System Risk in Medical Device Design

Abstract:

Medical devices designed for human use can be used to help patients overcome illness or disease and improve their quality of life. Researchers are working with 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). 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[13,14]. 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 (fig.1). 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]. **Figure 1. shows the FMEA process for identifying the risk hazards from the design process and mitigation of the risk caused by the identified hazard during designing process.**

S. No	Hazard	Hazardous situation	Harm	Severity Level	Possibility of Occurrence	Risk	Risk Evaluation/Acceptability Decision	Risk Control Option	Implementation of Risk Control	Residual Risk Severity	Probability of Occurrence after Risk Control	Residual Risk Acceptance	Risk acceptance after risk control measure	Information supplied to user/patient	Risk arising from risk control measure
1a	Improper Design	Inadequate Design Control	Mal-union, non-union or delayed union which may lead to device failure.	S4	O3	Not Acceptable	Improper design is not acceptable. However, with proper design controls it can be verified and evaluated before transfer to production.	Design Control	Design control covers appropriate design review, Design verification and design validation prior to design transfer. Reference: Design and Development	S4	O1	AFAP	With strict compliance with Design and Development controlling all D&D stages: input, output, review, verification, validation and design transfer, current risk is acceptable	Not Applicable	No

Fig 1.FMEA Process for design hazard.

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



Fig.2 FMEA Process chart

The above given Figure 2. shows the 360° approach process chart for the failure mode and effect analysis. Every process related to the FMEA starting from the data collection to effectiveness analysis is shown in the process chart.

3. Risk management overview

Risk management essentially becomes an endeavour 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.3 shows the risk management process chart for system risk in Medical Device Industry.

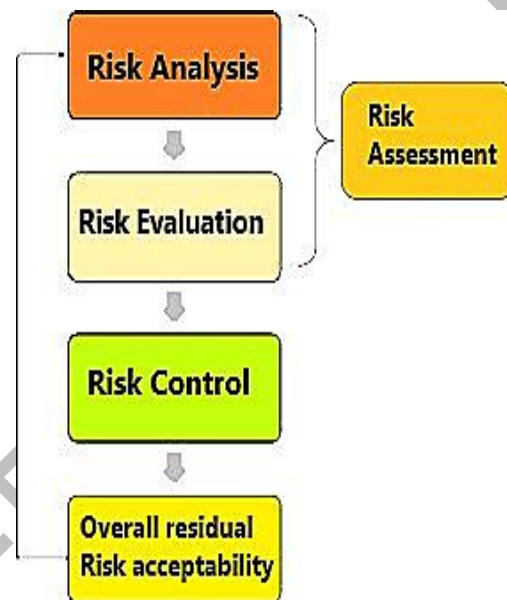


Fig.3 Risk management Process chart for system risk in Medical Device Industry

4. Risk assessment process in system

The risk assessment process that can be easily used here, risk (R) = severity (S) * Occurrence (O) identifies 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. 4 and Figure 5.

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 ($R = S \times O$) to evaluate the risk.

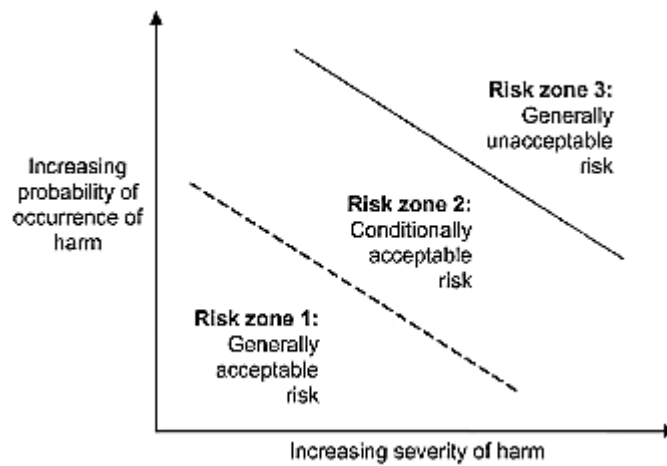


Fig.4Figure representing the Risk Zones

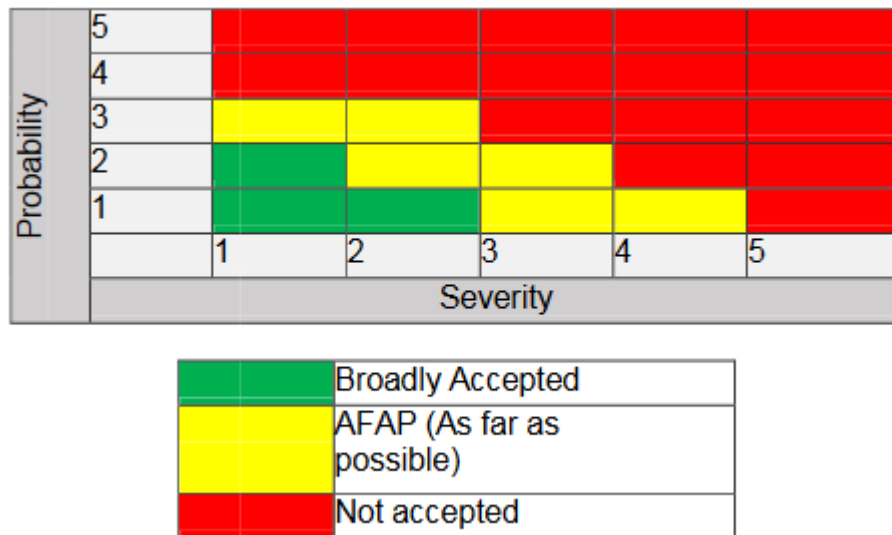


Fig.5 Risk Zones as per the acceptability

Through using the above given 5x5 matrix the probability of occurrence and severity level is categorized which helps in calculating the RPN(Risk priority number) number. It is a numeric assessment of a risk assigned to a process.

In the above given figure 5. the risk which falls under the Green zone is broadly acceptable, Yellow region is As far as possible and Red region is Not acceptable.

5. Detecting risk during design process of Medical device

The risk occurring during the design and development of medical device can be detected by proper assessment of the device design from every possible aspect of the risk hazards. The designer should keep in mind that every possible hazard associated with the designing phase of device should be properly communicated to the risk manager. The risk manager should work on the mitigation of the risk along with the designer during the very first stage of designing. Once the risk is mitigated on the designing phase it will help in mitigating the other associated risks related to the design of the medical device, which occurs once the device is placed in the market. Risk management prospective with design and development should be done properly for mitigation of the risk, it will result in an positive outcome of a safe medical device for human use. The proper mitigation of risk hazard occurred during designing phase is shown in the Figure.1 FMEA for design.

Conclusion:

The subjects covered have been utilized in the design and development of medical devices. FMEA is a major technique for risk analysis, thus it is widely used as risk management tool in medical device industries .

The key to a good medical device design is to get started as soon as possible for proper assessment of risk and to mitigate the identified risk. 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.

REFERENCES

1. Sharma, Akash, and Gaurav Luthr. "Importance of Risk Communication and Risk Analysis in Medical Device Industry." *Journal of Pharmaceutical Research International* (2021): 32-41.
2. Burton, John, Fergal McCaffery, and Ita Richardson. "A risk management capability model for use in medical device companies." *Proceedings of the 2006 international workshop on Software quality*. 2006.
3. EN ISO 14971:2019. Medical devices— application of risk management to medical devices, European Committee for Standardization.
4. Clinical investigation of medical devices for human subjects. Part 1: General requirements (EN ISO 14155-1:2003) and Part 2: Clinical investigation plans (EN ISO 14155-2:2003). European Committee for Standardization.
5. Borah, Kaustav Jyoti. "Medical device design-an introduction to systems risk." *International Journal of Intelligent Systems Design and Computing* 1.1-2 (2017): 186-197.
6. Sawyer, Dick, et al. "An introduction to human factors in medical devices." *US Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health* (1996).
7. Singh, Karnika, and Praveen Selvam. "Medical device risk management." *Trends in Development of Medical Devices* (2020): 65-76.

8.Gardner-Bonneau, Daryle. "THE STATUS OF HUMAN FACTORS IN THE MEDICAL DEVICE INDUSTRY." *Human Factors Interventions for the Health Care of Older Adults* (2001): 217.

8.Malhotra, Sameer, et al. "Designing the design phase of critical care devices: a cognitive approach." *Journal of biomedical informatics* 38.1 (2005): 34-50.

9.Van der Peijl, Jorien, et al. "Design for risk control: the role of usability engineering in the management of use-related risks." *Journal of biomedical informatics* 45.4 (2012): 795-812.

10.Dhillon BS, Rajendran MU. Human error in health care systems: bibliography. *INTERNATIONAL JOURNAL OF RELIABILITY QUALITY AND SAFETY ENGINEERING*. 2003 Jan 1;10:99-118.

11.Rasoulifar, Rahi, et al. "Proposal of a new Design Methodology in the Surgical Domain." *ICED'07, International Conference On Engineering Design*. 2007.

12.Burton, John, Fergal McCaffery, and Ita Richardson. "A risk management capability model for use in medical device companies." *Proceedings of the 2006 international workshop on Software quality*. 2006.

13.Mc Caffery, Fergal, John Burton, and Ita Richardson. "Risk management capability model for the development of medical device software." *Software Quality Journal* 18.1 (2010): 81-107.

14.Zhao, Xiuxu, and Xiaoli Bai. "The application of FMEA method in the risk management of medical device during the lifecycle." 2010 2nd International Conference on E-business and Information System Security. IEEE, 2010.