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# Risk Management in Medical Device Industry

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***Authors' contributions***

*This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.*

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***Review Article***

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## ABSTRACT

In spite of the fact that risk management has developed into an essential component of the process of developing medical devices, as mandated by both domestic and international regulations and standards, there is still no all-encompassing model that describes how risk management in the development of medical devices ought to be approached, particularly in terms of the types of risks that ought to be addressed. This is due to the fact that risk management has developed into an essential component of the process, which is mandated by both domestic and international regulations and standards. The present focus of risk management in the industry of developing medical devices is on technical risks, such as product, usability, and development process hazards. This is done in compliance with the norms and laws of standards. On the other hand,

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non-technical risks, such as those associated with businesses and projects, are not given nearly enough consideration. This review focuses on the risk management in medical device industry.

*Keywords: Risk management; medical devices; medical device industry; risk management steps.*

## 1. INTRODUCTION

The lifecycle of product development for medical devices always includes risk management as an essential component. It provides assistance to those responsible for the development of medical devices by assisting them in ensuring that their products are reliable, perform as intended, and do not pose a risk to either patients, operators, or the environment. To put it another way, the primary goal of the risk management cycle is to lessen the likelihood of an error occurring in the product by taking various preventative measures [1,2].

In the field of medical device development (MDD), risk management (RM) was very recently validated as a new success factor with a growing importance, despite the fact that earlier studies on MDD success factors did not place an emphasis on this particular component [3]. The increasing trend toward the digitization of medical equipment introduces an entirely new set of dangers, some of which may not have been adequately considered in the past. In recent years, it has come to light that medical equipment increasingly rely on more contemporary information and communication technologies (ICT), such as wireless communication and Internet access, which has led to the confirmation of the security dangers that are caused by intentional threats [4]. Because if these associated risks continue to be unknown, without suitable countermeasures, further data breaches and even malicious attacks may occur, putting patients' lives in jeopardy, putting their information in jeopardy in terms of confidentiality, integrity, and availability, and not to mention hindering the success of MDD projects. A more thorough RM framework that would ensure wider risk coverage is required because if it isn't in place, further data breaches and even malicious attacks may occur. Devices manufactured by MDD companies are being recalled from the market on a regular basis due to failures in product quality, which has an effect on practically all of the main actors in the medical device supply chain [5]. According to Thirumalai and Sinha [6], the primary causes of these failures may be traced back to manufacturing faults, functional problems, packaging issues, and software glitches. This creates the possibility for a risk to the patients and personnel who use these devices in terms of their health. A recent study conducted by Kamisetti [7] explores 21 medical devices that have been recalled in the United States due to the presence of a sensible risk that could result in major health issues or even death. As a result, in order for MDD companies to avoid such possible failures and make the most of the success of their projects, it is essential to identify the characteristics that systematically enhance the possibility of the risk triggers occurring at the early stages of project development. In light of the fact that MDD can have a considerable influence on human lives and that MDD start-ups in particular have a hard time getting off the ground, the scope of risk management in MDD among start-ups needs to be thoroughly researched in order to improve risk identification and prompt risk mitigation [8-10].


**Picture 1. Risk, come from probability of occurance and severity of harm**

## 2. MEDICAL DEVICE CLASSIFICATIONS AND RISKS ASSOCIATED WITH THEM

The Food and Drug Administration established the processes for medical device classification that are included in Part 860 of the medical device classification manual. The FDA classifies medical devices according to the possible 17 risks that they may impose on the user. These classifications are also dependent on the level of regulatory control that the FDA has over the device before it can be released onto the market. The higher the classification, the greater the associated risk, and the greater the amount of controls imposed by regulators [11,12].

Class I devices are deemed to pose the least amount of risk to patients since their designs are straightforward, they are easy to produce, and they do not pose any danger to patients. These devices are merely subject to general restrictions and do not have any records of probable damages that they have caused in the past. In addition, they do not typically need to undergo pre-market notice because the general controls that are in place are robust enough to ensure both their safety and their efficiency. General controls are defined by the FDA as including the following provisions: section 501 (adulteration), section 502 (misbranding), section 510 (registration), section 516 (banned devices), section 518 (notification and other remedies), section 519 (records and reports), and section 520 (general provisions) [13-16].

Class II devices pose a higher level of danger than Class I ones, although they are nevertheless permissible for use in human life support. Therefore, the Food and Drug Administration (FDA) requires manufacturers to fulfill sufficient evidence that these devices are assured to be safe and effective by establishing the following: proliferation of performance standards, post market surveillance, patient registries, development, and distribution of guidance documents that include pre market notification in accordance with the 510(K) act for market submission. In addition, the FDA (2004) requires manufacturers to fulfill sufficient evidence that these devices are assured to be safe and effective. In the event that the device's producer is unable to provide convincing evidence that the product is safe for consumers to use, the Commissioner may request additional actions and evidence. X-ray machines, pumps, and surgical drapes are all examples of devices that fall into the Class II category [17-19].

18 Among the several classifications of medical equipment, Class III devices pose the greatest risk to patients because they are the gadgets that are utilized to keep people alive. One example is the use of new heart valves, as well as breast implants filled with silicone gel. According to the Food and Drug Administration, medical devices that fall under this category are often required to have both a Pre-Market Approval (PMA) and a 510(K) clearance before they may be submitted to the market. When it is deemed appropriate to do so, the Commissioner is also authorized to request additional proof of effectiveness and safety [20,21].

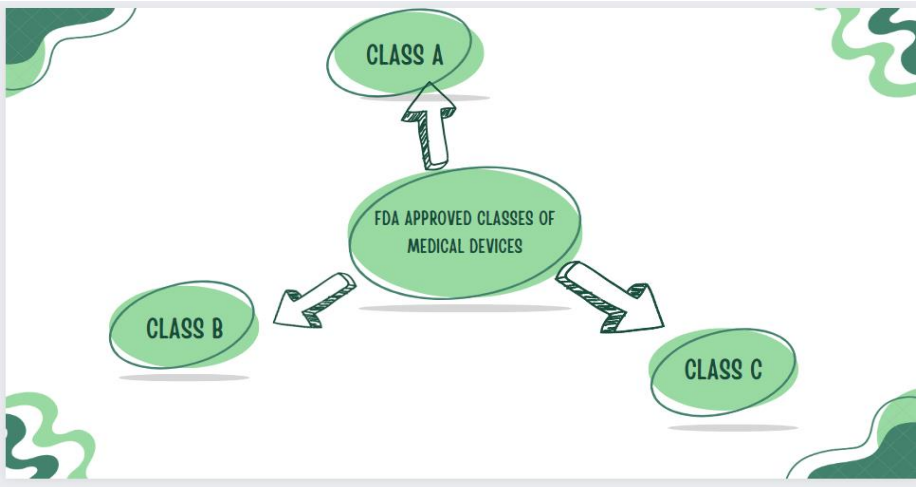


**Fig. 1. Classification of medical divices**

1. **Regulatory Requirements for Risk Assessment and Management:** According to Medical Device School, it is of the utmost importance that producers of medical devices not only conduct a comprehensive risk assessment process of a medical device but also make certain that a reliable risk management strategy is also implemented. From the moment an idea for a product is conceived all the way until the time when it is put on the market and discarded, this approach makes it possible to easily handle any potential risks that may be associated with that product [22]. The numerous regulations and standards that pertain to risk management in medical devices, as well as the establishment of the Global Harmonization Task Force (GHTF) [23], whose mission it is to harmonize these regulations and standards globally, will make it simpler to put the risk management process into action.
2. **Steps of Risk Management Process:** There are many different rules, processes, and practices that are utilized in the process of systematically analyzing, evaluating, controlling, and monitoring risks in medical devices. Let us begin by gaining an understanding of the usual processes that are required to develop a comprehensive risk management lifecycle for medical devices.

## 2.1 The Framework and the Planning for the Risk Management of Medical Devices

A risk management framework is required to be built in order to define any risk management process in line with the requirements imposed by organizations such as FDA or ISO. This framework outlines the procedure that will be followed in the development of the device, as well as the roles and duties of those who are involved in the process of developing the device. Along with this, the framework for risk management in medical devices also requires the establishment of appropriate documentation of the risk management strategy. This is one of the requirements for the framework [24,25].

## 2.2 The Analysis of Risk

An assessment of the potential risks posed by medical devices will be of use to the device producers in focusing their attention on the product's intended application. This will assist in focusing on the necessary steps, as well as providing an overview of the pertinent dangers (possible sources of injury) [26]. At this point in the process, it is necessary to identify any potential risks as soon as feasible so that a risk assessment may be performed. It is interesting to note that in evaluating risks, the process of identifying potential damages should not only consist of finding the causes but also the potential danger related to them [27].

## 2.3 Evaluation of Risk

Quantifying and assessing a risk will be made easier by first determining its level of severity and its likelihood of occurring. If there is a potentially dangerous circumstance (one that is highly likely to occur), but the potential for harm is quite low, and there is another situation in which the likelihood of experiencing harm is rather high, then it is a good idea to properly visualize the risk on a matrix in order to determine which risk should be addressed first [28].

## 2.4 The Management of Danger

After the risk has been recognized, the subsequent phase is to exercise control over it; this is the stage where risk reduction strategies are put into action. The purpose of risk control is to reduce the severity of a risk to an acceptable level, often known as mitigating the risk [29]. A risk can be reduced or managed in a number of different ways, including the following:

It is possible to do so in a number of ways, one of which is by modifying the design of the product to a point where the risk is reduced; however, this solution is not always feasible. The subsequent choice is to incorporate protective measures in line with a certain danger in order to cut down on the number of occasions on which harm occurs. The very last thing that has to be done is either marking the dangers associated with a certain item or adding instructions to the user manual for that device [30,31]. It is essential to keep in mind that if the product is redesigned with the intention of reducing the hazards associated with it, there is a possibility that the number of dangers associated with the product will increase [32].


**Fig. 2. Risk managment steps**

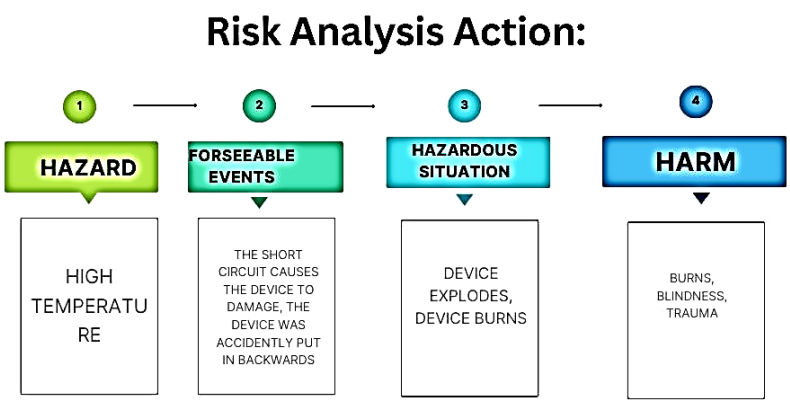


**Fig. 3. Risk analysis**

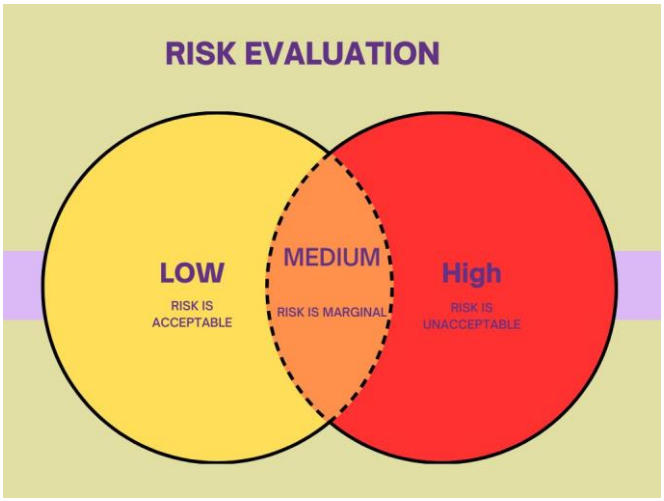


**Fig. 4. Risk analysis and evaluation**

#### 2.4.1 Control and monitoring of risk-taking activities

In order for a device to satisfy the standards that were established in the past for what constitutes an acceptable level of risk, measures need to be taken to either get rid of or significantly lower the risks that are associated with it. To accomplish this goal, one or more risk mitigation strategies could be implemented. Control of risks can start as early as the design input phase and extend throughout the entire lifetime of the medical device [33]. A predefined hierarchy of risk controls may be prescribed by certain regulatory schemes, and these controls should be evaluated in the following order:

- Information for safety, such as warnings, maintenance schedules, etc.
- Inherent safety built into the design of the product.
- Protective measures built into the item or its construction.

Throughout the entirety of the product's life cycle, the maker keeps a close eye on the risks to determine whether or not they continue to be acceptable and whether or not any new dangers or risks are found. Information is often received in the form of production, complaints, customer feedback, etc., and used for monitoring, thus having an efficient quality management system that is also properly defined is essential [34].

#### 2.4.2 Controls to reduce the likelihood of adverse events

Protective measures include operating modes that are preset by default, and information for safety includes warnings printed on labeling. Intervention is required for a wide variety of measures, including, but not limited to [35]:

- The appropriate response for the circumstances, such as a patient-specific reaction.
- Timeliness.

### 2.5 Reports and Related Documentation

Documenting the risk management plan and methods constitutes both the final and most critical phase in the process. It is also essential to emphasize that the documentation of the risk management plan is not confined to the preliminary stages of the project [36]. It is necessary for the document pertaining to risk management to include all of the steps, reports, evaluations, and diagrams that were developed for the risk management planning process [37]. Even after the product development process has been finished, you should still keep your documentation up to date because the risk management strategy is an integral component of the entire product development lifecycle process [38]. Along with this, it is also essential to document the efficiency of the control actions while maintaining a close eye on the risks that have arisen as a direct result of the implementation of the risk management actions [39].

## 3. KEY ELEMENTS OF CHOOSING YOUR RISK MANAGEMENT PANEL

An integral component of the risk management planning process is the selection of a team including individuals who will be responsible for conducting the assessment of potential risks. As previously said, these individuals are responsible for evaluating the potential risks associated with your medical equipment and determining appropriate methods for risk mitigation. It is imperative to assign this crucial task to proficient persons who have received training in risk management methodologies [40]. The FDA does not provide a specific list of required job titles for inclusion in the medical device development team. However, it is advisable to assemble a team with individuals from diverse disciplines who possess a comprehensive understanding of all aspects of the device, including its construction and appropriate usage scenarios [41].

- This may involve a combination of individuals who represent:
- The regulatory department that you mentioned
- The process of ensuring and maintaining the desired level of quality in a product or service.
- The field of engineering encompasses the application of scientific and mathematical principles to design, develop, and
- The process of producing goods through the conversion of raw materials into finished products, commonly referred to
- Human factors engineering, sometimes known as ergonomics, is a multidisciplinary field that focuses on the design and optimization of systems, products, and environments to enhance human


**Fig. 5. Risk management**

- The field of marketing encompasses various strategies and techniques employed by organizations to promote their products or services

If a firm is unable to assemble a comprehensive risk management team internally, it may be necessary to seek external advice as well.

## 4. SOFTWARE FOR THE MANAGEMENT OF RISK IN MEDICAL DEVICES

Due to the increasing number of devices that have implemented the software, risk management needs to begin with an early stage of planning and strategizing. In the healthcare business, there are a variety of medical devices that are used to manage essential situations, such as diagnostic, patient monitoring, and therapeutic. The operation of software on top of the device hardware will continue to be a primary consideration in determining the total number of devices that will be functioned [42,43].

Even the solutions that have all of the features, including electronic and mechanical software, might take a significant amount of time to design. Devices that have a straightforward use case will have a user interface that is easier to use, will be designed more quickly, and will be simpler to implement. The proliferation of software in the medical industry will, as a result of data breaches and open access, also raise the risks connected with it [44-46]. The regulation of medical equipment is based on a number of core principles, the most important of which is risk management. These principles apply equally to legacy medical devices as well as software that is a medical device. Risk management is the glue that binds together all of these different regulations and standards, which is why the regulatory framework will contain so many of them. In ISO 14971, essential concepts of risk management software for medical devices are outlined. These principles encompass all of the necessary legislation and standards, and they apply to legacy devices as well as software as a medical device (SaMD). However, due to the quick cycles of growth and change that are inherent in the software industry, there are certain concerns that must be taken into account when it comes to risk management [47,48].

## 5. THE SIGNIFICANCE OF A RISK MANAGEMENT PLAN

The initial phase of effective risk management commences prior to the analysis of the physical device in question. The process commences with the development of a risk management plan. It is imperative for your firm to establish a standardized operating procedure that encompasses the risk management process. The implementation of this comprehensive plan is recommended for all products inside the organization [49,50]. Furthermore, it is imperative to generate an individualized risk management plan for each medical equipment. In this context, a comprehensive analysis will be conducted, encompassing all potential risks related with the specified product [51,52].

It is imperative to implement the risk management plan at an early stage of development in order to avoid last-minute efforts to complete the FDA submission and overlook

potential safety issues. Developing these preparations in advance offers a comprehensive framework for effectively managing risks. Moreover, this approach fosters objectivity as the methodology is explicitly defined, so mitigating the influence of personal biases or idiosyncrasies associated with a particular undertaking [53,54].

## 6. WHAT DOES ISO 14971 STAND FOR?

The ISO 14971 standard is the international risk management standard that is universally acknowledged for medical devices. The most recent revision of this standard, known as ISO 14971:2019, is the topic of discussion in this article. This standard is presently regarded as the most advanced available [55,56]. The processes for identifying, analyzing, and reducing risks that are linked with the utilization of medical devices are provided by the ISO 14971:2019 standard. Despite the fact that it is not obligatory, it is the most popular and widely recognized standard in the business world to demonstrate conformance to when discussing the requirements for product safety. This article offers a summary of the standard; nevertheless, it should not be utilized as a replacement for the official content of the standard [57].

The entire lifecycle of a medical device is taken into consideration by a risk management system, just as it is by a quality management system. This means that the development, production, and application of the device are all taken into account. In addition, although the deployment of a quality management system is not specifically required by ISO 14971:2019, risk management is typically considered to be an essential component of an effective quality management system [58]. In order to be in compliance with ISO 14971:2019, a risk management system needs to be developed, implemented, and maintained over the entirety of the product lifetime. Additionally, all processes and outcomes need to be documented and kept in a risk management file. The system for managing risks will incorporate procedures for analyzing, evaluating, and controlling potential dangers [59].

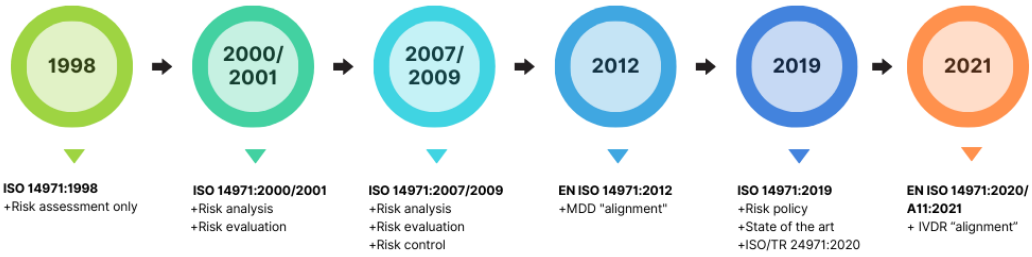


**Fig. 6. ISO timetable**


**Fig. 7. Clauses of ISO**

## 7. CONCLUSIONS

It is the responsibility of the producers of medical devices to guarantee the quality and reliability of the items they sell. Manufacturers as well as patients who use medical devices have a vital part to play in the maintenance of the risk–benefit balance. This can be accomplished by ensuring that products are designed, tested, labeled, prescribed, and utilized in a manner that maximizes benefits while minimizing risks. Regardless of whether medical devices are being developed in the United States, the European Union, Canada, or anywhere else in the world, producers of medical devices are required to implement a risk management strategy that is compliant with ISO 14971. ISO 14971 is recognized and accepted by every worldwide regulatory organization. The cycle of risk management consists of numerous parts, including risk analysis, risk evaluation, risk control, and the determination of how much residual risk is acceptable. It is also beneficial to do postmarket risk assessments after the product launch in order to make decisions regarding whether or not field action is required in the event that an unfavorable event takes place. In most cases, efforts pertaining to risk management will result in the discovery of chances to enhance the performance of the device. It is possible that carrying out a risk analysis as part of the design process for a medical device could result in significant advantages, which in turn could be used to compensate for some or all of the costs associated with carrying out risk-mitigation procedures. When it comes to managing risk, there is always a choice between different options. Controls that are implemented through either hardware or software are typically seen as more efficient given that they are more dependable than human controls. However, due to the fact that all medical devices require human involvement in order to function properly, it is necessary to do an acceptable risk assessment. Reducing the amount of routine human intervention will both lower the risk and increase the effectiveness of the system. A cost-benefit analysis needs to be done to determine whether or not it is worthwhile to automate activities that can be carried out by persons.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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