American Journal of Botany and Bioengineering
https://biojournals.us/index.php/AJBP
ISSN: XXXX-XXXX

Meeting International Standards for Medical Device Reliability and Risk Management

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Received: 2024 29, Jul
Accepted: 2024 28, Aug
Published: 2024 06, Sep

Abstract: In the design and development of safe, effective medical devices, reducing risk and ensuring reliability are a manufacturer's primary responsibility. The advanced technology inherent in medical devices and their production means that all aspects of the system–including mechanics, electronics, software, and hardware–must be evaluated for reliability. What's more, due to the significant impact that a new medical device technology can have on human lives, every aspect of its development–from design and prototyping through manufacture, distribution, disposal, and decommissioning–must adhere to strict quality standards that are documented and traceable to functional and safety requirements. These standards may apply not only to manufacturers, but also to vendors, suppliers, contractors, OEMs, third parties, and others in product development and distribution.

Keywords: International standards, equipment reliability, medical equipment, health care.

Introduction

Dimensions of medical device risk

Medical devices–which may be defined as any equipment used to diagnose, treat, or monitor patient health–are subject to a variety of complex quality and safety analyses due to the potential significant impact on human lives. Numerous standards throughout the medical device industry require the use of a documented process to identify, analyze, and eliminate or control the risks associated with medical device hardware, software, and electronics. This process, known as risk management, must address potential risks throughout the entire product lifecycle of medical device products, including development, manufacture, maintenance, and disposal or decommissioning.

Not only is the implementation and documentation of a risk management process required for the premarket approval of medical devices, it also helps protect companies against steep liability damages by providing evidence that risk was assessed during product development and that every reasonable measure was taken to control it. Medical device regulations and guidelines ISO 14971 and GHTF/SG3/N15R8 call for the thorough documentation, via a risk management file, of all risk management activities performed by the manufacturer.

Not only must they be fully documented, these activities must be traceable to an initial risk management plan, which must adhere to the risk management process required by regulatory bodies. Assessing and reducing the risks associated with medical devices also helps to reduce the total impact of wide-ranging product recalls, including financial costs as well as reduced customer satisfaction and a damaged company reputation. Most importantly, companies are morally and ethically obligated to know the impact that a product will have on human safety and wellbeing before the product is released to the public.

The following examples describe a few of the many dimensions that an assessment of medical device risk and reliability must consider:

- Part failures: The failure of one part or component of a medical device can lead to system failure and may result in patient injury or death. For example, if a feedback mechanism in a therapeutic medication delivery system fails, a patient may receive incorrect or even lethal doses.
- Process failures: Fully operational devices can inflict harm when used improperly, such as X-ray machines when proper measures are not taken to protect the patient.
- Human impact: The potential harm caused by a part or process failure may extend not only to the patient but to the device operator and others in the environment, as in the case of a highly flammable oxygen source.
- Device application: Each device may have many different applications, uses, or environments. For instance, defibrillators are now commonly available in public places for use by nonprofessionals in cases of emergency. These devices require different risk controls when used by different operators. Similarly, a device as simple as a blood pressure cuff can be used in many situations, including emergency, rehabilitative, surgical, and more. Each possible application of a device must be considered during risk analysis.
- Complex technology: The advanced technology used in medical devices and in their production requires that all aspects of the system–including mechanics, electronics, software, and hardware–must be evaluated for reliability. Consider the many systems that comprise an ultrasound device, including hardware that comes in direct contact with a patient, sophisticated electronics that emit high frequency waves, and advanced software transmitting findings to a healthcare professional via computer. If all of these complex systems are not working together properly, the device may fail at its crucial role in patient diagnosis.
- Product lifecycle: Every aspect of the product development lifecycle for a medical device–from design, prototyping, and manufacture through distribution, decommissioning, and disposal–must adhere to strict quality standards that are documented and traceable. For example, taking extra care during the design stage to select the most reliable parts cannot prevent errors in device assembly. Therefore, all aspects of product development must be considered and controlled during risk management.
- Industry-wide standards: These standards may apply not only to device manufacturers, but also to their suppliers, contractors, OEMs, third-party manufacturers, and others associated with product development and distribution. If device parts are manufactured by one company, assembled by another, and distributed by a third, all three parties should participate in the risk

management process to ensure that every possible risk is managed before the device is sent to market.

- Significant stakeholders: A wide range of potential stakeholders are affected by the reliability of a medical device, including medical practitioners, healthcare institutions, government, industry, patients, their family members, and others

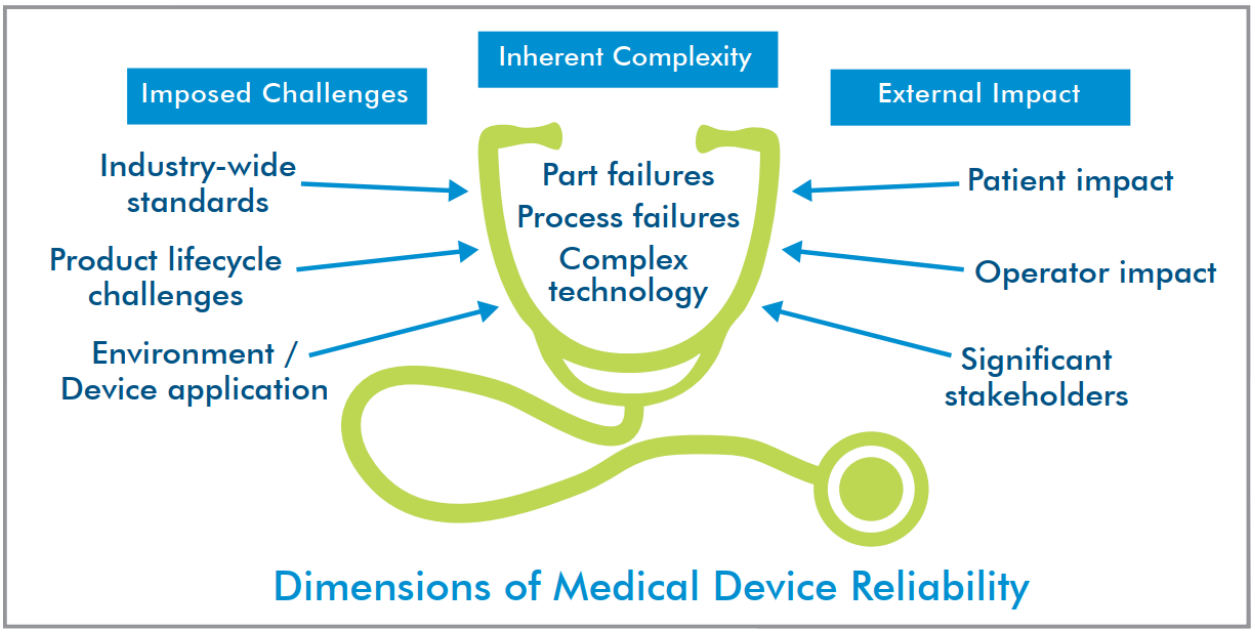

Figure 1: The multiple dimensions of medical device reliability:

Imposed Challenges, Inherent Complexities, and External Impact

The role of ISO 14971 in defining risk management

Risk management in the medical device field is primarily defined by standard ISO 14971. According to this standard, risk management involves the systematic application of policies, procedures, and practices to the task of analyzing, evaluating, controlling, and monitoring the risk inherent in medical devices. Risk management is an iterative process that should evaluate all aspects of the product's lifecycle and must be implemented and documented over the course of the design, development, prototyping, manufacture, and even postproduction phases of a product's lifecycle to ensure that no new or unexpectedly severe risks go unmanaged.

GHTF/SG3/N15R8: Four phases of reliability management

In an effort to incorporate the requirements of risk management set forth in ISO 14971 into the requirements of a quality management system, the Global Harmonization Task Force (GHTF) defined four main phases of risk management in its guideline GHTF/SG3/N15R8. These four phases may be summarized as follows:

- Phase 1: Establishing acceptable and unacceptable levels of risks
- Phase 2: Identifying and analyzing the risks associated with the device from all potential sources
- Phase 3: Evaluating these risks in light of the definitions of risk acceptability defined in Phase 1
- Phase 4: Implementing control measures to eliminate risks or mitigate their effects, and monitoring the effectiveness of these controls once they are implemented

Each phase defined in GHTF/SG3/N15R8 summarizes multiple steps, and their associated definitions, set forth in ISO 14971. Both documents require the creation of a risk management file, which comprises the thorough documentation of each step in the risk management process. All of the steps summarized by the four phases and required in the risk management file documentation are described in full below:

1. Risk management plan: Defining acceptable/unacceptable levels of risk

ISO 14971 requires that a risk management plan be created at the start of the risk management process to fully document how each required step will be carried out by the manufacturer. This plan must include criteria for risk acceptability based on the manufacturer's existing policy for determining acceptable and unacceptable risks. These important criteria will provide the basis for accepting a certain risk when the probability of its occurrence or its potential harm cannot be eliminated, or rejecting the risk as being too hazardous and therefore requiring its elimination or mitigation.

2. Risk analysis: Identifying and estimating risks throughout the product lifecycle

Risk analysis is a systematic, documented process beginning with a description of the device, the person doing the analysis, and the scope and date of the analysis. A description of the intended use and foreseeable misuse of the device follows, to establish a baseline from which potential risks–either from proper or improper use–could emerge.

3. Risk evaluation: Comparing estimated risk to acceptable / unacceptable levels of risk

Every risk that is identified and estimated, it must be evaluated with an eye to the criteria for risk acceptability outlined in the original risk management plan. If the risk is deemed unacceptable, it must be eliminated or mitigated using risk control measures. If the risk is deemed acceptable, it must be justified according to these levels of unacceptable and acceptable risks.

4. Risk control: Designing control measures to eliminate or mitigate risks

During this process, decisions are made and measures implemented to reduce or mitigate risk to within the levels specified in the risk management plan. This very important process comprises several distinct steps, which themselves must be documented in the risk management file:

- Analyze risk control options
- Implement risk control measures
- Evaluate residual risk
- Perform a risk/benefits analysis
- Review the effects of risk control measures
- Review completeness of risk control measures

5. Overall residual risk acceptability

Once the steps for risk assessment, evaluation, and control are performed for each risk identified in a medical device, the overall residual risk of the product must be analyzed for its acceptability in regards to the standards set forth in the risk management plan. If all remaining residual risks are deemed acceptable, they must be documented and disclosed in any information or instructions accompanying the product, as well as in the risk management file. If the overall residual risk is not deemed acceptable, it must be fed back as input into the risk assessment part of the risk management process for reevaluation and control.

6. Risk management report: Documenting how all required risk Management steps were performed

Prior to production, a new medical device typically requires approval by national or international regulatory agencies. The production of a risk management report, which documents that all required steps have taken place in accordance with the original risk management plan, is required by these regulatory bodies. This becomes a part of the risk management file.

7. Production and post-production information: Monitoring the device postmarket for any additional risks

To gain approval of a medical device for production and distribution, evidence of an established, documented, and maintained system to collect and review information about the device throughout its production and postproduction phases is essential. Although it would appear that risk management activities have all been performed, in reality they have just begun. It is just as important to know that the device will be manufactured in accordance with established standards and perform in accordance with these standards.

ISO 14971

As an internationally recognized standard for medical device manufacturers, ISO 14971 establishes risk management as an essential part of ensuring the safety and reliability of medical devices. Derived from ISO 13485, which requires a documented product realization process, ISO 14971 specifies that this process should include risk management. This standard:

- Specifies a framework manufacturer must use to identify the hazards associated with a medical device, including in vitro diagnostic medical equipment
- Requires companies to conduct and document a risk management process, which it defines fully as described above
- Applies to all stages of the product lifecycle, from its design and development through its decommissioning and disposal
- Calls for the evaluation and assessment of risks to patient, operator, and others; and extends to the equipment itself, other equipment, and the surrounding environment
- Mandates device monitoring throughout production and postmarket use, including the reevaluation of device risks should new or unexpected hazards arise

IEC 60601

This standard identifies required safety standards for electrical medical equipment, which may be defined as equipment connected to a power supply and used in diagnosis, treatment, or monitoring of a patient; which makes physical or electrical contact with the patient, transfers energy to or from the patient, and/or detects energy transfer to or from the patient. This standard also extends to accessories used with such equipment. This standard:

- Sets specific requirements for electromagnetic compatibility, human factors such as the usability of devices, and specific types of applications such as devices used during surgery
- Defines hazards ranging from electrical shock, mechanical sources of harm, radiation, ignition or fire, and excessive energy output
- Requires the use of risk controls including safety by design, protective measures taken during manufacturing, and instructions or labeling information for safety
- Identifies performance requirements–that is, characteristics of a system which are required to maintain residual risk
- Mandates risk analysis activities for specific areas of product design, including protection against shock, protection against the entry of liquids, and the use of flammable materials

Finally, Windchill Quality Solutions adhere to the quality standards for software used in the development and production of medical devices, including 21 CFR Part 11, which requires the use of closed systems, administrator controls define the level of access for every group or user in the system, password-protected login at the terminal level, and audit tracking capabilities to identify and record each change made to the system. The development team responsible for Windchill Quality Solutions performs the in-depth testing processes required by verification and validation, and can supply the FDA-required documentation of this compliance upon request.

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