CHAPTER 3

Why Do Risk-Management?

Abstract

There are many good reasons to do risk management. In addition to making safer products, risk management can help reduce the cost of design and development by identifying the safety-critical aspects of the design early in the product life cycle. Risk management is a legal requirement in most countries, without which it would not be possible to obtain approval for commercialization of medical devices. In the unfortunate situations when people are injured by medical devices, the first place that lawyers would look is the risk management file of the device.

Keywords: Legal; regulatory; harmonized standards; risk-based; recall; field corrective action; moral; ethical

Whether you are aware of it or not, you are constantly managing risk in your daily life. For almost every action that we take, we internally evaluate the benefit of that action vs. the risks (or cost) of that action. If we believe the benefits outweigh the risks, we take that action. Else, we don't. Consider the simple action of driving to work in your car. You consider the benefit of comfort and speed of getting from home to work vs. the risks of getting injured or killed in a car crash. In general, the chances of getting into a serious accident are fairly small, compared to the benefit of commuting in your car. But now imagine you are in a war-torn country where there are explosive devices buried in the roadway. Now the calculus changes. The risks are higher than the benefits, and you would likely choose to walk off-road instead.

The medical device industry is required to evaluate the potential safety risks due to the use of a medical device against the potential Benefits of that device. Regulatory approval of a medical device requires demonstrating that the risks of the device are outweighed by its Benefits. Formal and systematic methods are used to make this determination.

Another important reason to do risk management is the progressive shift in the industry where more and more decisions are risk-based. For example, decisions on Field Safety Corrective Actions, decisions on Corrective and Preventive Actions, and Product Hold Orders. Risk-based decisions are rational and defensible. In many aspects of product development, e.g., design choices, or test sample-size determination, risk is a good discriminator and basis for decision-making. Moreover, the European Medical Device Regulation (EU MDR) [2] takes a preference for a risk-based approach to evaluation of manufacturer's technical documentation, and oversight and monitoring of the manufacturers. How can one make risk-based decisions, if one doesn't know the risks? Risk management offers the answer.

DOI: https://doi.org/10.1016/B978-0-323-85755-0.00003-5

3.1 LEGAL AND REGULATORY REQUIREMENTS

3.1.1 United States

In the United States, the governing law is United States CFR Title 21, part 820. Title 21 is about foods and drugs, and part 820 is about Quality System Regulations. This law requires that all finished medical devices be safe and effective. The burden of proof is on the manufacturer. Prior to ISO 14971, there were many methods used by manufacturers to provide evidence of safety. There was no consistency and the quality of the evidence varied widely.

On January 14, 2020 the FDA recognized ISO 14971:2019 [9]. However, the FDA will continue to accept declarations of conformity to the previous version, ISO 14971:2007, in support of pre-market submissions until December 25, 2022. As a recognized standard, conformance to ISO 14971 is sufficient proof of medical device safety for the FDA.

3.1.2 European Union

In the European Union, until May 25, 2021 manufacturers can choose either of two regulatory channels for the approval of their medical devices.

Channel 1 – MDD/AIMDD

Directive 93/42/EEC, also known as the Medical Device Directive (MDD) [3] compelled the member States to pass laws that were consistent with the MDD. Article 3 of the MDD required that medical devices must meet the essential requirements set out in Annex I. Stated briefly and simply, the Essential Requirements of *Annex I* stipulate that medical devices:

1. Be safe when used as intended by the manufacturer.
2. Have benefits that outweigh their risks.
3. Reduce risks as far as possible.

There was also a counterpart to MDD [3] for active implantable medical devices. It was called Active Implantable Medical Device Directive (AIMDD) [4]. AIMDD was similar to MDD, but was focused on Active Implantable Medical Devices.

Article 5 of the MDD stated that compliance with the Essential Requirements of *Annex I* could be presumed, if a medical device was conformant with relevant harmonized standards that are published in the *Official Journal of the European Communities* [5].

Channel 2 – Medical Device Regulation (MDR)

The EU MDR [2] is a regulation which applies to all member states in the European Union. Unlike the MDD, it does not compel member states to interpret it and pass laws that are consistent with it. The MDR is a Regulation which is applicable as is, hence not subject to varying interpretations by member states.

Annex I, Chapter I of EU MDR [2] has similar requirements to MDD [4]. Stated briefly and simply, the General Safety and Performance Requirements stipulate that medical devices:

1. Be safe and effective when used as intended by the manufacturer.
2. Their risks be acceptable when weighed against the Benefits to patients.
3. The risks be reduced as far as possible without adversely affecting the Benefit-risk ratio.

Similar to the MDD/AIMDD, the EU MDR confers a presumption of compliance with the MDR requirements if a manufacturer is in conformance with the relevant harmonized standards.

Harmonized Standards – According to MDCG 2021-5 [6], Harmonized European standards in the field of healthcare engineering, including medical devices, are developed by the two relevant European standardization organizations: the European Committee for Standardization (CEN) for most types of medical devices, and the European Committee for Electrotechnical Standardization (CENELEC) for medical electrical equipment.

According to Article 10 of the Standardization Regulation (EU) 1025/2012, the European Commission may request one or several European standardization organizations to draft European standards. This is the necessary legal basis for the development of harmonized European standards in support of the requirements of EU legislation, and to allow publication in the *Official Journal of the European Union* (OJEU) [5].

During the standardization process, specific assessment of the draft standards under development is carried out by the "Harmonized Standards (HAS) consultants," as technical experts supporting the European Commission, to ensure the compliance of the draft harmonized standards with the relevant EU legislative framework and with the relevant standardization request (mandate).

CEN and CENELEC propose to the European commission the publication of references to such standards in the OJEU [5]. The Commission carries out the final assessment on compliance of these proposed standards with the requirements of the legislation, as well as the relevant standardization mandate or request, taking into account the assessment reports by the HAS consultants to decide whether to publish references to the European standards in the OJEU [5]. Publication in the OJEU [5] makes the standard harmonized.

Conformance to harmonized standards is voluntary. Products designed and manufactured according to applicable harmonized standards benefit from a presumption of conformity with the relevant regulations. This creates an advantage for the manufacturers in demonstrating compliance with regulations, and a similar advantage for the Notified Bodies and

Competent Authorities in assessing compliance with the regulations, thereby leading to quicker and easier regulatory approvals of medical devices.

Notified Bodies are accredited entities who assess conformity to harmonized standards. For a list of the Notified Bodies refer to the website: https://ec.europa.eu/.

Directive 98/79/EC on in vitro diagnostic medical devices (IVDMDD), is applicable from June 7, 2000 until May 25, 2022. From May 26, 2022, Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), is fully applicable.

Each country in the European Union has a Competent Authority who approves medical devices for commercialization. Upon approval by a Competent Authority, a medical device can be CE (Conformité Européenne) marked.

3.1.3 MDD/AIMDD and Transition to EU MDR

EU MDR [2] was promulgated on May 26, 2017. There was a 3-year transition period after which AIMDD [4] and MDD [3] would no longer be effective and only MDR certification would be possible. This transition period was to end on May 26, 2020. But for a variety of reasons, the date of application was postposed to May 26, 2021. The date of application for IVDR is May 26, 2022. From May 26, 2017 to November/December 2018 only MDD/AIMDD certification was possible. Thereafter, until May 26, 2021, it was possible to choose MDD/AIMDD or MDR [2] certification.

There is a 3-year grace period after May 26, 2021 during which products that were certified to MDD/AIMDD can be still manufactured and sold – until May 26 2024. Thereafter, there is only a 1-year period until May 26, 2025 to sell off any inventory of MDD/AIMDD certified products.

3.2 BUSINESS REASONS

3.2.1 Cost Efficiency

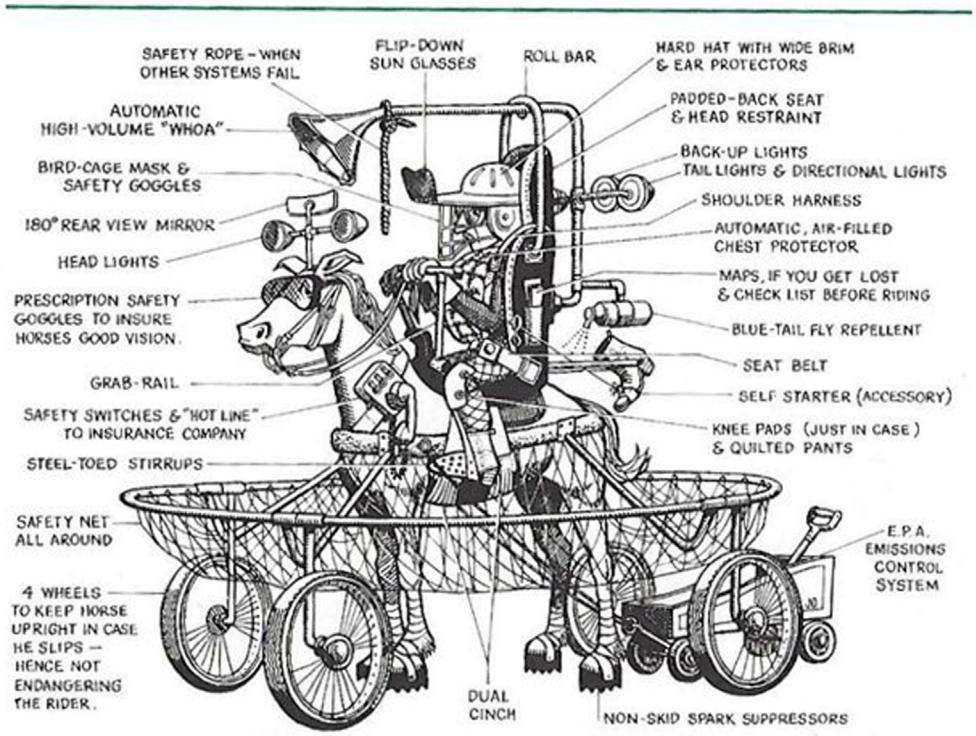
One of the main benefits of risk management is gaining knowledge of what the risks of a medical device are, where they are, and how big they are. With this knowledge, the product development team can focus their engineering resources on the areas of

highest risk. Furthermore, good risk management practices can help detect design-flaws that have a safety impact, early in the product development process. The sooner a design-flaw is corrected, the less expensive it is to fix it.

Competition and economic incentives drive the industry for speed to market. But history suggests that speed does not justify compromise on the safety of programs. For example, excess focus on schedule resulted in the Space Shuttle Challenger disaster in 1986.

Manufacturers want to make their products as safe as possible. But without clear knowledge of the risks of a device, the tendency is to operate based on fear and to over-engineer in an abundance of caution. This is costly, especially when the over-engineering is done in areas that are of low/no risk.

The cartoon in Fig. 1 was drawn by J.N. Devin in 1972. Although it gives a comical view of over-engineering, there are some lessons hidden in there. It shows when a good intention can go awry to the point of making a product useless.



Mr. James N. Devin, Independence, Missouri. © 1972. Reproduced with permission.

Figure 1 Over-Engineered Cowboy.

3.2.2 Avoiding Recalls and Field Corrective Actions

Safety violations are the main reason for Field Safety Corrective Actions (FSCA), such as product recalls. Product recalls are very expensive, and expose manufacturers to lawsuits and potentially large fines, settlement costs, and legal fees. Moreover, the reputation of a manufacturer may become tarnished and future sales hampered.

Good risk management practices can reduce the probability of harming people or the environment, and thus avoid recalls.

One of the most important benefits of risk management is that it provides leading indicators for potential future problems. In many cases a manufacturer realizes only after an Adverse Event, that they are in trouble and facing a lawsuit or punishment by Regulatory bodies. Risk management enables manufacturers to identify the highest risks associated with their products and be able to forecast the probability of Serious Adverse Events.

3.2.3 Better Communications

An unexpected side benefit of risk management is improved communication. In most companies the product development teams become siloed, which means poor communication among the various disciplines, such as electrical engineering, mechanical engineering, clinical, sterilization, etc. Because risk management is a team effort, it tends to bring the various disciplines to the table to work together toward safer products. Many very useful and enlightening discussions happen during the risk management work meetings.

3.3 MORAL AND ETHICAL REASONS

Our patients trust us with their lives. They expect that we do our utmost to make devices that are safe and effective. It is our moral and ethical duty to apply good risk management practices so we deliver the safest possible products to our patients. Effective and safe devices earn the trust of medical device makers' customers.