Design Inputs uncovered

Requirements, risks and regulations

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Requirements, risks and regulations

Requirement management is considered a key discipline in medical device development. In this article, we will elaborate on the medical device specific aspects of requirement management and how the concepts of intended use, regulations and risk management become an integrated and vital part of the requirement elicitation process.

Due to the high level of safety required by medical devices, requirement management plays a decisive role in medical device development. As it is an inherent property of medical products to expose users and patients to elevated risks, the importance of safety and risk reduction is clearly reflected in the regulations governing the development of medical devices. Both ISO 13485 and FDA 21 CFR 820.30 explicitly spell out detailed rules on how requirements must be elicited and managed in order to increase safety and reduce risk.

Requirements, risks and regulations

In many cases, these detailed rules correspond to established best-practices. As an example, the following well-known practices are included in ISO 13485:

- **Make sure the requirements are complete, unambiguous and not in conflict with each other.**
- **Review the requirements for adequacy and approve them in a review process.**
- **Keep the requirement documents under document control.**
- **Subject the requirements to rigorous change management.**
- **Include the requirements in the system traceability.**

However, ISO 13485 also stipulates requirement elicitation methods that are relatively specific to the medical device industry. In section 7.3.3, we find that our requirements must include:

- **Functional, performance usability and safety requirements according to the intended use.**
- **Applicable statutory and regulatory requirements (as well as the results from the risk management) and standards.**
- **Where applicable, information derived from previous similar designs and other requirements essential for design and development**
- **Applicable output(s) of risk management.**
- **As appropriate, information derived from previous similar designs.**
- **Other requirements essential for design and development of the product and processes.**

A number of interesting aspects are worth noting. The standart not only enumerates the methods to use in order to keep in requirements in good order. It also points out explicit areas to inspect in order to uncover requirements that reduce risk. With this in mind, we shall take a closer look at how three of these areas (intended use, regulations and risk management) influence the requirement eliciting process for medical device development.

Requirements and Intended Use

According to ISO 14971, a product's intended use is defined as the „use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer".

In other words, the manufacturer must define for what purpose and for which circumstances the product is intended. For example, a test that measures a certain antigen exposes the user to widely different risks, depending on if the test is used for screening, diagnosing or monitoring the disease. The intended use serves as the basis for the classification of the product. Both FDA and EU use classifications to categorize products according to the risk they pose to the patient. Generally, the higher the classification, the higher the level of safety required, implying an increased number of mandatory activities and deliverables on behalf of the medical device producer.

Development costs and time lines are thus significantly affected by the classification level derived from the intended use. The purpose for which the product is intended also has several implications for the requirement scope.

Firstly, the intended use heavily influences the product's risk classification and subsequently the number and strictness of regulations applied. As we shall see below, the resulting set of regulations has a strong influence on the number and nature of derived requirements.

Secondly, the intended use directly and indirectly defines both the product's working environment as well as user characteristics which are of particular interest when eliciting safety-related requirements.

Thirdly, the intended use implicitly defines the practical usage of the device. The usage is the basis for extracting scenarios, which serve as input to the risk management process. The output of the risk analysis often translates into new, safety-enhancing requirements.

Fourthly, during requirement reviews, the intended use is utilized as baseline when judging the adequacy and correctness of the already derived requirements.

Requirements and regulations

When deriving requirements from regulations, the starting point is usually to sort out the regulations that are applicable to the product in question, which, as we have seen above, is affected by the intended use. This is often more easily said than done. By evaluating existing similar products, it is sometimes possible to gain an overview of applicable regulations.

If this approach should not be feasible, a standart inventory might be necessary, roughly conducted in the following manner:

1. Specify the geographic areas in which the device will be marketed.
2. For each of countries in these regions, acquire an-exhaustive list of standarts and regulations.
3. For each of these regulations, assess its applicability either by considering the device's physical characteristics (does it contain a laser? does it use electric power?) or its intended use (is it used in a sterile environment?).
4. For the applicable regulations, derive the appropriate requirements.

This may sound like an exhaustive task and it is true that it must not be underestimated. However, note that not all applicable regulations have an impact on requirements. Many regulations are concerned with processes rather than the characteristics of the product itself. Furthermore, a norm inventory is not the only means of eliciting applicable regulations. The applicability of a regulation is sometimes established by the risk management process. In the example IEC 15233, the regulation claims that a specific graphical symbol is to be applied to the device if this measure reduces a risk according to the risk analysis. I n this case, the regulation applies only if it has been concluded by the risk management.
As regards to the formulation of regulatory requirements, it is good practice to include a norm-reference in the requirement rational. However, pay attention to the wording. It is not uncommon to find the requirements written in the following pattern,

"The product shall comply with standart so-and-so".

Note that this type of formulation has several drawbacks. First, it is only comprehensible to people closely familiar with the regulation. Second, it does not explicitly state any characteristic about the device, which makes it difficult to verify whether the requirement has been fulfilled at the verification stage. Using a formulation like.

"The product shall <have the characteristic X →, in accordance with standart so-and-so"

successfully preempts both these disadvantages while still keeping a clear reference to the norm in question.

Requirements as output of the risk management

The risk management process is one of the most powerful techniques for uncovering safety-critical areas and to develop safety increasing measures. The earliest iteration of the risk analysis process starts with considering the medical device's intended use, its characteristics, and its working environment and derive usage scenarios there of. Throughout the course of the risk analysis process a number of risk control measures are generated which are intended to reduce risk.

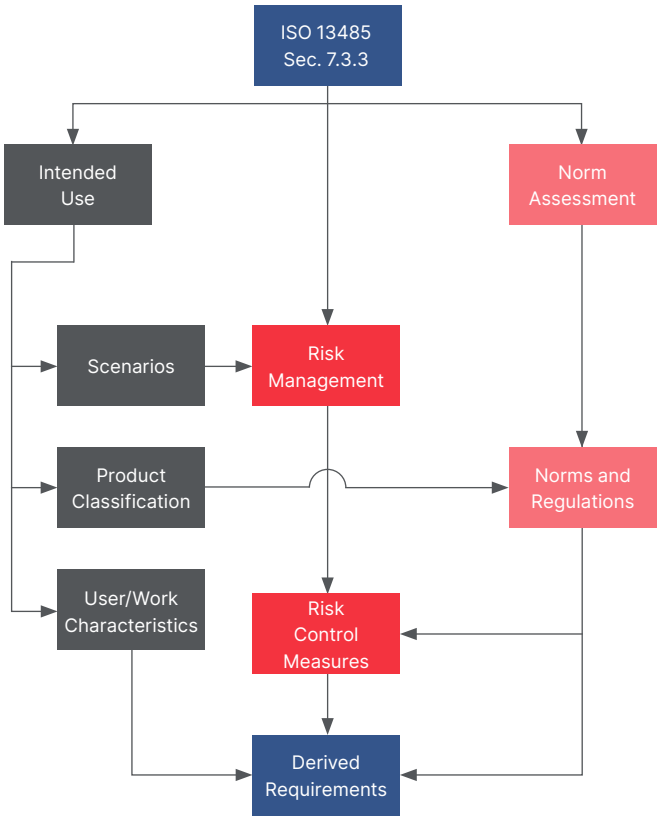
The resulting risk control measures shall, according to ISO 13485 section 7.3.3, be considered when eliciting safety-enhancing requirements. Some regulatory schemes prescribe a fixed hierarchy of risk control measures that should be examined in the following order:

- **Inherent safety by design.**
- **Protective measures in the device or its manufacture.**
- **Information for safety, such as warnings, etc.**

Regardless of whether a fixed hierarchy is used or not, the requirements derived from the risk control measures intrinsically enhance safety. It is worth noting that this process is inherently iterative since, in many cases, the requirements derived from risk control measures generate new input to be considered the next iteration of the risk analysis.

Conclusion

The enhancement of patient safety, being a central aspect of medical device development, has a major impact on the requirement management process. Norms such as ISO 13485 identifies several activities used to derive safety enhancing requirements. Risk management as well as standarts and regulations are brought in to reinforce the process and to ensure that an enhanced patient safety is resulting from the requirement elicitation. We also recognize the intended use as a major driver in establishing which regulations to apply and which hazardous situations to consider. If managed correctly, these mutually supportive disciplines will form the core of a safety enhancing requirement management process.



Literature

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ISO 14971:2019 Medical devices – Application of risk management to medical devices

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