



White paper:
**Medical device risk management
using ISO14971**

This White Paper provides an overview of the medical device standard ISO 14971 concerning the application of risk management to medical devices.



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Risk Management and ISO 14971

ISO 14971 is an international standard for the application of risk management, by a manufacturer, to medical devices. (This includes in vitro diagnostic (IVD) medical devices).

It has wide adoption in the medical device industry. In various worldwide markets it has formal recognition as a compliance standard, where it can be used to meet aspects of risk related regulatory and compliance requirements.

Risk management, in an ISO 14971 context, can be considered as a comprehensive and systematic application of risk analysis, risk evaluation, risk control and on-going monitoring of risk.

Although risk management is often thought of in relation to patient risk, ISO 14971 is also concerned with the risk to other people, including operators, other equipment and the environment.

ISO 14971 provides a way in which a manufacturer can assess risk and make informed decisions. It does not require that a medical device be entirely risk free, nor does it set down a specific acceptance level in relation to risk.

Which version?

Along with all international performance standards, ISO 14971 is subject to periodic review and update. These revisions are adopted at national and supranational levels but not always at the same time or in the same way.

When ISO 14971 is used to meet regulatory requirements, the version to comply with may differ depending on the regulatory regime and potentially, the type of medical device. It is important to determine which version to comply with – some examples of versions currently accepted by regulatory authorities are listed in this section 1. In determining to use ISO 14971, there may be additional on-going requirements to comply or to consider complying with updated revisions.

This version is, for example, formally accepted by the Australian Therapeutic Goods Administration (TGA) as a method to identify the risks associated with the use of a medical device. It is also formally recognized by the United States Food and Drug Administration (FDA) as a consensus standard and can be used to support a premarket application.

In markets requiring compliance to European directives, the current version of the harmonised standard (i.e. it can be used as a presumption of conformity to aspects of the various device directives), is EN ISO 14971:2012 – the main body of the standard is identical to the 2007 (corrected) version but it differs in regard to having informative annexes, which indicate the relationship between the standard and the various device directives. These annexes contain important implications with respect to regulatory requirements – for example, ISO 14971:2007 allows the manufacturer to discard negligible risks; however the medical device directives interpretation requires the manufacturer to assess all risks.

ISO 14971:2007 – a synopsis

Lifecycle approach

Critically, risk management is intended to be applied throughout the life-cycle. The life-cycle includes design, production and post-production; this includes the period after product is placed on the market.

The participants

The standard recognises that appropriate subject matter experts must be engaged in the application of risk management. This may require utilising or engaging external personnel – for example where a key process or material is supplied by an external company and there is a lack of internal knowledge. This is critical to the risk management process. No matter how well designed the process for implementing risk management, knowledge gaps may result in a risk management output that is not fully effective. It would also be open to challenge during an audit or inspection.

It is the responsibility of management to ensure appropriate personnel are assigned and that sufficient resources are available. Management is also responsible for risk acceptability and periodic review relating to risk management.

Risk Management Plan

To comply with ISO 14971, a risk management plan is required. This helps to ensure that risk management is completed throughout the product life-cycle. A minimum set of requirements is specified – scope, responsibility and authority, review requirements, acceptability criteria, verification, data collection from production and post-production. Additional requirements may be included as required.

Risk Management File

The documents and records related to the risk management process for a medical device must be included in a risk management file. As with common documentation practice, it doesn't need to contain all the documents and records but it must at least contain references to each of the outputs.

The risk management process

It is imperative to ensure that the medical device is known, i.e. the intended use or intended purpose and safety related characteristics, so as to determine hazards and hazardous situations that may arise. It is important to include a consideration of expected and unexpected conditions; including use, misuse and fault conditions. This phase is risk analysis.

The process continues to risk evaluation of hazardous situations and then the identification of appropriate risk controls.

Consider the following example relating to a syringe:

First, the risk is analysed. As the syringe is used to inject solutions into the body, a key characteristic is that the device is sterile. A potential hazard is microbial contamination. This could occur due to device not being subject to an appropriate sterilisation process. The hazardous situation is that microbial contamination enters the patient during syringe use and the resulting harm could include infection or death.

A risk evaluation is conducted based on the severity, likely of occurrence and probability of detection. Based on risk acceptability criteria, risk mitigation is identified as being required. Risk control measures are identified –this would include selection of appropriate sterilisation method / cycle, validation of the sterilisation process to appropriate standards, implementation of relevant in-process controls, e.g. indicators and monitoring, for product manufacture and sterilisation, appropriate infrastructure, establishment of packaging and load configurations, establishing review / acceptability criteria and implementation of procedures and training for routine processing, review and release.

Note: This is a limited example for explanatory purposes - additional risks and control would also need to be considered e.g. in relation to integrity of the terminally sterilised packaging

The impact of identified risk controls must also be assessed with regard to new hazards or hazardous situations being generated or in relation to the impact on existing risk determination. This may result in feedback into risk analysis. It is a requirement that risk controls are appropriately implemented.

Ultimately, the manufacturer must demonstrate that the benefit outweighs the risk.

Risk management applies to device design but also to the process used in the manufacture of a medical device. Risk management continues after the product is produced and after it is placed on the market.

Feedback and information from production, post-production and state of the art developments are used as a feedback loop into the risk management process.

The standard provides useful, non-exhaustive guidance to aid the reader in the risk management process. This includes a range of tools that may be applied – for example Failure Modes and Effects Analysis (FMEA).

The pre-prepared informative guidance in the standard should not be relied upon to be absolute; there is no substitute for expert opinion and analysis and risk analysis must always be adapted to specific circumstances. It is however possible to employ a standardised approach.

Relationship with other standards

As it is a well-established standard, ISO 14971 is often cross-referenced from other standards. This includes, but is not limited to, ISO 13485 and IEC 60601-1.

ISO 14971 is directly referenced in ISO 13485:2003 Medical Device – Quality management systems – Requirements for regulatory purposes, although it does not mandate its use. Risk management is however required as part of ISO 13485.

ISO 14971 is also directed referenced in IEC 60601-1:2005 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance. However in this case, compliance to ISO 14971:2000 is required before certification to IEC 60601-1 will be granted.

Correspondingly IEC 60601-1 is a tool in relation to risk management.

References

ISO 14971:2007: Medical devices – Application of risk management to medical devices

EN ISO 14791:2012: Medical devices – Application of risk management to medical devices

ISO 13485:2003: Medical Device – Quality management systems – Requirements for regulatory purposes

IEC 60601-1:2005: Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance

Sources

Links used within this document are prone to change. Please refer to the appropriate source for the most recent information. We endeavour to keep an up-to-date record of information at www.pharmout.net



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