

Free Guide

ISO 14971: Medical devices



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What is ISO 14971?

ISO 14971 sets guidelines for risk management in the manufacture of both software and in vitro medical devices. It outlines a process for ensuring safety throughout a product's lifecycle by identifying, evaluating, controlling, and monitoring potential hazards.

These hazards include those related to:

- Biocompatibility
- Data and systems security
- Electricity
- Moving parts
- Radiation
- Usability

Who needs an ISO 14971 certification?

An ISO 14971 certification is often necessary for manufacturers of medical devices, including those involved in their design, production, and distribution.

While not necessarily mandatory by law, the standard does ensure that medical devices meet international safety standards by effectively managing and mitigating risks throughout a device's lifecycle. As such, it is often required by regulatory bodies and industry standards around the world.

How to earn an ISO 14971 certification

To get certified in ISO 14971, an organization typically develops and implements a risk management plan that aligns with the standard. The organization will then conduct an internal audit.

If successful, the organization will contact a certification body, then schedule and undergo an external audit. Once the external audit has been passed, the organization will receive an ISO 14971 certification.

Renewal requirements for ISO 14971 certification

ISO 14971 certifications are typically valid for three years, after which time an organization must undergo another external audit. This ensures that your organization's risk management plan is kept updated and aligned with the ISO 14971 standard.

The benefits of ISO 14971 certification

ISO 14971 certifications offer several benefits to organizations. Some key advantages include the following.



Regulatory compliance

ISO 14971 certification ensures compliance with international regulatory requirements, allowing organizations market access in regions like the EU and US. This helps avoid legal issues and expedites the approval process for medical devices.



Risk reduction

By helping organizations identify and manage risks associated with medical device production, an ISO 14971 certification minimizes the likelihood of device failures. This leads to safer medical devices, reduces liability, and enhances patient safety, resulting in protection for both users and manufacturers.



Improved medical device quality

Implementing ISO 14971 improves the overall quality of medical devices by integrating risk management into the design and production processes. This results in more reliable products, increased customer satisfaction, and a stronger competitive position in the market.

Challenges in earning an ISO 14971 certification

Implementing ISO 14971 may pose several challenges to organizations. They include the following.



Resource intensive

Achieving ISO 14971 certification requires significant investment of time and resources. Organizations must develop, implement, and maintain a comprehensive risk management process, which can especially be a challenge to smaller operations.



Complex documentation

Maintaining detailed and accurate documentation is a core requirement of ISO 14971. Ensuring all risk management activities are thoroughly documented and kept current can be challenging, especially for organizations that manufacture complex products or have multiple product lines.



Continuous training

Ensuring that all employees are trained and updated on ISO 14971 processes is essential but challenging. Regular training programs are necessary to ensure staff understand and comply with the standard's risk management protocols.

Tips and strategies for earning an ISO 14971 certification

Here are a few tips for preparing for an ISO 14971 certification:

- Purchase and read the [ISO 14971 standard](#) in full
- Define a clear risk management process that is aligned with the ISO 14971 standard
- Perform a skills gap analysis to determine the skills your organization needs to implement and adhere to an ISO 14971-approved medical device risk management process

Resources for ISO 14971 certification

For more information and guidance on ISO 14971 certification, you can refer to the following resources.

International Organization for Standardization (ISO). The [ISO 14971 page](#) on the official ISO website provides the ISO 14971 standard document, news updates, and additional resources.

Accredited certification bodies. To pursue ISO 14971 certification, you can reach out to accredited certification bodies that offer certification services in your region. These bodies have the expertise to guide you through the certification process. You can find a list of accredited certification bodies on the website of the [International Accreditation Forum \(IAF\)](#).

Regulatory authorities. Various regulatory authorities worldwide, such as the [U.S. Food and Drug Administration \(FDA\)](#) in the United States or the [European Food Safety Authority \(EFSA\)](#) in the European Union, are closely related to ISO 14971. These regulatory bodies may use ISO 14971 as a reference or align their regulations with the standard, as well as offer scientific advice and risk assessments for medical devices.

Skills management for ISO 14971 certifications

AG5 stores all certifications in the cloud, providing all authorized personnel with access to the right version of approved certifications. This helps you easily keep track of all data and documentation related to an ISO 14971 certification across your organization.

Using AG5's skills management software, you can monitor the status of any type of certification that is relevant to your workforce, leveraging intuitive dashboards that provide you with a clear understanding of exactly what is needed to keep your employees skilled and safe.

Frequently asked questions about ISO ISO 14971 certifications

What is the scope of an ISO 14971 certification?

ISO 14971 covers the entire production life cycle of both software and in vitro medical devices.

Is an ISO 14971 certification mandatory?

ISO 14971 is not mandatory by law, but is required by many of the major international regulatory agencies, such as the FDA.

How long does it take to obtain an ISO 14971 certification?

Certification time will vary depending on an organization's size preparedness, but typically takes several months to a year.

What are the cost considerations for ISO 14971 certification?

Cost considerations for ISO 14971 certification include training, audit costs, and costs for changing or implementing new technology into the production process.

What is the validity period of an ISO 14971 certification?

ISO 14971 certifications are typically valid for three years.

Can an ISO 14971 certification be integrated with any management systems?

Yes, ISO 14971 certification can be integrated with ISO 13485, the quality management system for medical devices.

How can you learn more about ISO 14971 certification?

Visit the [ISO 14971 page](#) on the official ISO website or the website of [International Accreditation Forum \(IAF\)](#).

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