ISO 14971: Risk Management of Medical Devices

4 – 8 January 2027
Rome (Italy)



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Ref: 3178_290313 **Date:** 4 – 8 January 2027 **Location:** Rome (Italy) **Fees:** 5200 GBP

Introduction

In today's healthcare and medical device sectors, effective risk management is crucial for ensuring the safety and effectiveness of medical devices. This comprehensive ISO 14971 training course focuses on ISO 14971: Application of Risk Management to Medical Devices, helping professionals understand how to identify, evaluate, control, and monitor risks throughout the lifecycle of a medical device. With a focus on quality risk management of medical devices, this course equips participants with the essential tools to comply with international standards, mitigate risks, and enhance the safety of their products.

Upon completion, participants will gain a solid understanding of the ISO 14971 process, from hazard identification to risk control and benefit-risk analysis. This training will allow you to implement a risk management system in line with ISO 14971 and ensure compliance with regulatory requirements. Whether you're a medical device manufacturer, a risk manager, or a quality control professional, this course will help you navigate the complexities of medical device safety standards and apply best practices to enhance patient safety.

Course Objectives

- Understanding ISO 14971: Define ISO 14971 and explain its relevance to the medical device industry.
- ISO 13485 and ISO 14971 Linkages: Identify the connections between ISO 13485 Quality Management Systems and ISO 14971 Risk Management.
- Risk Management in the Product Lifecycle: Explain how risk management is applied throughout the product lifecycle of medical devices.
- Risk Management Terminology: Define key terms and concepts within the ISO 14971 standard.
- Stages of Risk Management: Outline the stages of the risk management process as specified in ISO 14971.
- Risk Management Deliverables: Describe the key deliverables expected during the ISO 14971 risk management process.



Course Outlines

Day 1: Introduction to Risk Management in Medical Devices

- Links of Risk Management to Regulatory Requirements: Learn how ISO 14971 links with other medical device regulatory standards.
- ISO 14971 and Other Standards: Understand the relationship between ISO 14971 and other international standards such as ISO 13485.
- ISO 13485 and Risk Management: Gain insights into the ISO 13485 standard and its role in medical device risk management.

Day 2: The Development of ISO 14971

- Why ISO 14971 for Risk Management: Discover why ISO 14971 is critical for managing risks in the medical device industry.
- The Lifecycle Approach: Understand the lifecycle approach to risk management for medical devices.
- Overview of ISO 14971: Deep dive into the ISO 14971 standard, terms, definitions, and general requirements.

Day 3: The Risk Management Process

- Risk Management Plan: Develop a risk management plan for medical devices.
- Risk Analysis: Learn to identify and assess risks associated with medical devices.
- Risk Evaluation: Evaluate the severity and likelihood of risks to determine their acceptability.
- Risk Control: Implement strategies for risk control to mitigate identified risks.

Day 4: Residual Risk Acceptability

- Risk Management Documentation: Learn the essential documentation required for effective risk management.
- The Risk Management File: Understand the importance of maintaining a Risk Management File.
- Post-Production Risk Management: Explore risk management processes after the device has been produced.
- IEC 60601-1:2005: Discuss the role of IEC 60601-1 standards in medical electrical equipment safety.

Day 5: Tools for Risk Management

- Failure Modes and Effect Analysis FMEA: Apply FMEA to identify failure modes and their potential impacts.
- Fault Tree Analysis: Learn how to use fault tree analysis to assess and manage risks.
- Hazard Analysis and Critical Control Points HACCP: Understand how HACCP can be integrated into medical device risk management.
- Summary and Conclusions: Recap the key points covered in the course and discuss best practices for applying ISO 14971.



Why Attend This Course: Wins & Losses!

- Enhance Risk Management Skills: This ISO 14971 training course offers essential knowledge on medical device risk management that will help you comply with industry standards, improve decision-making, and ensure the safety and effectiveness of your products.
- Learn ISO 14971 Application: Understand ISO 14971: Application of Risk Management to Medical Devices and how to integrate risk management processes into every stage of the product lifecycle.
- Quality Risk Management in Medical Devices: Gain a thorough understanding of quality risk management of medical devices and how to mitigate risks associated with device manufacturing and post-production.
- Practical Tools for Risk Management: Learn the practical tools like FMEA, fault tree analysis, and HACCP, which are crucial for managing medical device risks.
- ISO 14971 Certification: Gain confidence in your knowledge of ISO 14971 and enhance your professional credentials with the ISO 14971 certification.

Conclusion

This course is designed for professionals seeking to improve their understanding of medical device risk management and gain valuable insights into the ISO 14971 risk management process. By attending this ISO 14971 training, participants will be equipped to manage and control risks throughout the lifecycle of medical devices, ensuring compliance with international standards and improving patient safety. Whether you are a medical device manufacturer, risk manager, or involved in medical device safety, this course will provide you with the expertise to navigate the complexities of risk management and enhance your organization's risk management efforts.

Ready to elevate your career with ISO 14971 training and apply best practices in medical device risk management? Join us and take the first step towards achieving ISO 14971 certification and mastering the skills required to manage medical device risks effectively.

