ISO 14971 Risk Management for Medical Devices Training

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Brussels (Belgium)



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Why This Course

Medical device manufacturers face increasing regulatory scrutiny and growing expectations for product safety and reliability. Effective risk management is not just a regulatory requirement—it is a critical component of ensuring patient safety, reducing product-related hazards, and maintaining global market access. ISO 14971:2019 provides the internationally recognized framework for identifying, evaluating, controlling, and monitoring risks throughout the entire lifecycle of a medical device.

The ISO 14971:2019 - Medical Device Risk Management Programme Intensive 1-Week Training equips professionals with the knowledge and practical skills needed to implement a compliant, robust, and efficient risk management process. Through hands-on exercises, real-world case examples, and structured analysis techniques, participants will learn to integrate risk management into design, production, and post-market activities, ensuring product safety and regulatory alignment.

What You'll Learn and Practice

By the end of this programme, participants will be able to:

- Understand the principles, structure, and requirements of ISO 14971:2019.
- Apply risk management techniques across the entire medical device lifecycle.
- Perform effective risk analysis, evaluation, and control activities.
- Implement and maintain a compliant risk management process within a QMS.
- Integrate risk management with design controls and post-market surveillance activities.

The Programme Flow

Day 1: Introduction to Risk Management

- Overview of ISO 14971:2019 and its purpose
- Key risk management principles, definitions, and terminology
- Understanding global regulatory requirements and complementary standards
- Lifecycle approach to risk management for medical devices



Day 2: Risk Analysis Techniques

- Identifying hazards and hazardous situations
- Conducting Fault Tree Analysis FTA
- Performing Failure Mode and Effects Analysis FMEA
- Using Preliminary Hazard Analysis PHA for early-stage risk identification

Day 3: Risk Evaluation and Control

- Applying risk estimation and evaluation methodologies
- Analyzing and selecting risk control options
- Evaluating residual risks and documenting results
- Conducting benefit-risk analysis for informed decision-making

Day 4: Risk Management Implementation

- Developing and executing a risk management plan
- Integrating risk management with design and development controls
- Creating and maintaining a comprehensive risk management file
- Ensuring full traceability across risk management activities

Day 5: Production and Post-Production Activities

- Monitoring risks through production and quality processes
- Integrating post-market surveillance and complaint handling
- Preparing risk management reports and documentation
- Continual improvement of the risk management process and system

Individual Impact

Participants will return with the ability to:

- Implement a fully compliant risk management process aligned with ISO 14971:2019.
- Conduct thorough hazard identification, risk analysis, and risk evaluation.
- Integrate risk management seamlessly with other quality system components.
- Address regulatory expectations confidently during audits and reviews.

Organizational Impact

Organizations benefit through:

- Stronger compliance with global medical device regulations.
- Improved product safety and reduced risk of adverse events.
- More efficient and documented risk control processes.
- Enhanced cross-functional collaboration between design, quality, and regulatory teams.



Training Methodology

This programme blends:

- Practical risk analysis workshops and scenario-based exercises
- Real-world case studies from the medical device industry
- Facilitator-led discussions and best-practice comparisons
- Templates, checklists, and tools for immediate workplace application

Beyond the Course

Upon completion, participants will be prepared to lead risk management activities within their organizations, support regulatory submissions, and contribute to safer, more reliable medical devices. They will return equipped with the skills and confidence to elevate their organization’s risk management maturity in alignment with ISO 14971:2019.

