ISO 14971 Risk Management for Medical Devices Training

Audit & Quality Assurance
Amsterdam (Netherlands)
18 - 22 Aug 2025

ISO 14971 Risk Management for Medical Devices Training

Ref: 3178_133570 **Date:** 18 - 22 Aug 2025 **Location:** Amsterdam (Netherlands) **Fees:** 4200 **Euro**

Course Description

This 5-day course provides comprehensive training on ISO 14971:2019 for medical device risk management. Participants will learn to apply risk management principles throughout the product lifecycle, from design to post-market surveillance. The course covers risk analysis techniques, evaluation methods, control measures, and regulatory compliance.

Learning Objectives

- Understand the principles and requirements of ISO 14971:2019
- Apply risk management techniques throughout the medical device lifecycle
- Develop effective risk analysis, evaluation, and control strategies
- Implement a compliant risk management process within a quality management system
- Integrate risk management with design controls and post-market surveillance

Course Modules

Day 1: Introduction to Risk Management

- Overview of ISO 14971:2019
- Risk management principles and terminology
- Regulatory requirements and standards
- Risk management process and lifecycle approach

Day 2: Risk Analysis Techniques

- Hazard identification methods
- Fault Tree Analysis FTA
- Failure Mode and Effects Analysis FMEA
- Preliminary Hazard Analysis PHA

Day 3: Risk Evaluation and Control

- Risk estimation and evaluation techniques
- Risk control option analysis
- Residual risk evaluation
- Benefit-risk analysis

Day 4: Risk Management Implementation

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- Developing a risk management plan
- Integration with design controls
- Risk management file documentation
- Traceability in risk management

Day 5: Production and Post-Production

- Risk monitoring and review
- Post-market surveillance integration
- Risk management reporting
- Continuous improvement of the risk management process

Practical Wins for Participants

- Ability to implement a compliant risk management process
- Skills to perform comprehensive risk analysis and evaluation
- Knowledge to integrate risk management with other quality processes
- Confidence in addressing regulatory requirements for risk management

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