

ISO 14971 Risk Management for Medical Devices Training

Audit & Quality Assurance
Maldives (Maldives)
01 - 05 Sep 2025

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ISO 14971 Risk Management for Medical Devices Training

Ref: 3178_129769 **Date:** 01 - 05 Sep 2025 **Location:** Maldives (Maldives) **Fees:** 4700 **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

A graphic of a chessboard with several chess pieces. A large gold king piece is in the foreground, with a silver pawn and a silver knight behind it. In the background, there are concentric circles emanating from a point on the board.

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