

ISO 14971 Risk Management for Medical Devices Training

Audit & Quality Assurance
Tunis (Tunisia)
07 - 11 Sep 2025

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A large, stylized image of chess pieces on a checkered board. In the foreground, a gold king piece stands prominently on a light square. To its left, a silver pawn piece sits on a dark square. Further back, another silver pawn piece is visible on a light square. The background features concentric circles radiating from behind the king piece, creating a sense of depth and focus.

ISO 14971 Risk Management for Medical Devices Training

Ref: 3178_128196 **Date:** 07 - 11 Sep 2025 **Location:** Tunis (Tunisia) **Fees:** 3700 **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

A graphic of a chessboard with several chess pieces (king, queen, rook, knight, and pawns) in gold and silver. The text 'UK Training PARTNER' is overlaid on the board.

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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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