# ISO 14971:2019 Medical Device Risk Management Course

29 March – 2 April 2027
Rome

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**Ref:** 1494_210303 **Date:** 29 March – 2 April 2027 **Location:** Rome **Fees:** 5700 Euro

## Overview

ISO 14971:2019 Medical Device Risk Management Course is a one-week advanced course for medical device quality, regulatory, engineering, clinical, manufacturing, supplier, and risk personnel, who leave with an ISO 14971 Risk Management File Pack. The course connects planning, intended use, hazards, hazardous situations, estimation, evaluation, controls, residual risk, benefit-risk, review, traceability, and production and post-production feedback. Agile Leaders Training Center presents ISO 14971:2019 application across the medical device lifecycle.

## Who Should Attend

- Teams responsible for medical device risk-management systems
- Personnel responsible for design and product safety engineering
- Functions responsible for quality and regulatory documentation
- Teams responsible for manufacturing, supplier, and change interfaces
- Personnel responsible for complaint, vigilance, and post-production feedback

The course assumes experience with medical device development or quality work and leaves out certification, clinical decision-making, and jurisdiction-specific regulatory approval advice.

## Departments and Industries

The course supports organizations that develop, manufacture, supply, or maintain medical devices and related software.

- Medical device and diagnostic product manufacturers
- Software as a medical device organizations
- Design, engineering, and product-development teams
- Quality, regulatory, clinical, and safety functions
- Contract manufacturing and critical supplier organizations

## Learning Objectives

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

- Apply ISO 14971:2019 terminology and lifecycle process
- Build risk plans and objective acceptability criteria
- Analyze hazards, event sequences, and hazardous situations
- Evaluate risk-control options and residual risks
- Use benefit-risk and overall residual-risk methods
- Integrate production and post-production information

## Course Agenda

## Day 1: Risk Management System and Planning

- ISO 14971:2019 Lifecycle Process Map
- Risk Management Policy and Responsibility Matrix
- Risk Management Plan Structure
- Objective Risk Acceptability Criteria
- Risk Management File Traceability Index

## Day 2: Risk Analysis and Estimation

- Intended Use and Reasonably Foreseeable Misuse Statement
- Safety-Related Characteristics Checklist
- Hazard and Hazardous Situation Identification Map
- Foreseeable Sequence of Events Model
- Severity and Probability Estimation Record

## Day 3: Risk Evaluation and Control

- Risk Evaluation Decision Matrix
- Inherent Safety, Protective Measure, and Information Hierarchy
- Risk Control Option Analysis
- Control Implementation and Verification Evidence
- Residual Risk and Introduced Risk Review

## Day 4: Benefit-Risk, Review, and Feedback

- Individual Benefit-Risk Analysis Record
- Overall Residual Risk Evaluation Method
- Risk Management Review and Report Checklist
- Production and Post-Production Information Plan
- Feedback, Change, and Risk Reassessment Loop

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## Day 5: ISO 14971 Application Practice

- Suggested Exercise: Risk Plan and Criteria Review
- Suggested Exercise: Hazardous Situation Analysis
- Suggested Exercise: Control and Residual Risk Decisions
- Suggested Exercise: Post-Production Reassessment
- Capstone Exercise: ISO 14971 Risk Management File Pack

## Practical Exercises

The course uses suggested activities with fictional electrical, software, diagnostic, reusable, and home-use medical device scenarios.

- Suggested activity: establish a risk plan, responsibilities, criteria, and file index.
- Suggested activity: map hazards, event sequences, hazardous situations, harms, and estimates.
- Suggested activity: select controls, verify implementation, and evaluate residual and introduced risks.
- Suggested activity: review production information and document whether reassessment is necessary.

## FAQs

### Who suits ISO 14971:2019 medical device risk management training, and what does it assume?

Medical device quality, regulatory, engineering, clinical, manufacturing, supplier, and risk personnel suit the course; it assumes experience with product-development or quality processes.

### How does ISO 14971:2019 risk management differ from general enterprise risk training?

ISO 14971:2019 addresses risks associated with medical devices across their lifecycle, including hazardous situations, harm, controls, residual risk, benefit-risk, and production feedback rather than financial or strategic business risk.

### What belongs in an ISO 14971:2019 risk management file?

An ISO 14971 risk management file should provide traceability to the plan, analysis, evaluation, controls, verification, residual-risk decisions, benefit-risk work, overall evaluation, review, report, and production and post-production activities.

### When is medical device risk reassessment needed?

Risk reassessment is needed when production, complaints, vigilance, service, usability, cybersecurity, supplier, change, scientific, or field information indicates new hazards, changed estimates, affected controls, or altered benefit-risk conclusions.

## Conclusion

Participants leave with an ISO 14971 Risk Management File Pack containing policy, plan, criteria, hazard, estimation, control, verification, benefit-risk, review, feedback, and traceability tools. The pack turns the standard's lifecycle process into connected records and decisions. It helps teams maintain risk evidence as device knowledge changes.