CONCEPT

Medical Device Risk Management and Quality Systems: ISO 14971 and ISO 13485

8 – 12 February 2027
Amsterdam - Zuidas business district hotel

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Ref: 265_11781 **Date:** 8 – 12 February 2027 **Location:** Amsterdam - Zuidas business district hotel **Fees:** 23500 SAR

Introduction:

Medical device risk management fails when hazards are listed once at design stage and never revisited, when quality records cannot show why a residual risk was accepted, and when complaints and field reports never reach the risk file. This Core Concept course takes manufacturers, distributors and hospital biomedical teams through device classification, an ISO 13485 quality management system and the ISO 14971 process: hazard identification, risk estimation and evaluation, risk controls, benefit-risk decisions and post-production information. Participants build a Device Risk Management File for a product from their own work.

Course Objectives:

- Classify medical devices by intended purpose and risk class and set the quality and documentation effort each class demands
- Apply ISO 13485 quality management system requirements to design controls, supplier control, traceability and process validation for devices
- Conduct hazard identification, risk estimation and risk evaluation for a device against documented risk acceptability criteria
- Select and verify risk control measures and justify residual risk through benefit-risk analysis as ISO 14971 describes it
- Feed complaints, post-market surveillance data and vigilance reports back into the risk file and trigger field safety corrective actions or recalls
- Compile a Device Risk Management File with the risk management plan, analysis records and risk management report

Target Audience:

- Quality assurance staff responsible for device quality management system records, CAPA and supplier control
- Regulatory affairs staff responsible for technical documentation and post-market reporting for device portfolios
- Design and development engineers responsible for design inputs, verification and risk control implementation
- Distribution and importer quality staff responsible for device storage, traceability, complaint handling and field actions
- Hospital biomedical and clinical engineering staff responsible for device acceptance, incident reporting and recall execution

Course Outline:

Day 1: Medical Device Fundamentals, Classification and Current-State Review

- Medical Device Definition, Intended Purpose and Accessories Boundary
- Risk-Based Device Classification Concepts: Class I, II and III Logic
- In Vitro Diagnostic Devices and Software as a Medical Device at Overview
- Device Life-Cycle Roles: Manufacturer, Importer, Distributor and Healthcare User
- Device Portfolio Current-State Gap Checklist

Day 2: ISO 13485 Quality Management System for Devices

- ISO 13485 Structure and Differences from ISO 9001 Requirements
- Design and Development Controls: Inputs, Outputs, Verification, Validation and Transfer
- Purchasing Controls and Supplier Evaluation for Critical Components
- Traceability, UDI Device Identifiers and Implantable Device Records
- Sterile Process Validation and Production Process Validation Protocols

Day 3: ISO 14971 Risk Management Process Application

- Risk Management Plan and Risk Acceptability Criteria Matrix
- Hazard Identification Using Intended Use, Foreseeable Misuse and Hazard Checklists
- Risk Estimation: Probability of Harm and Severity Scoring Tables
- Failure Mode and Effects Analysis and Fault Tree Analysis for Device Hazards
- ISO/TR 24971 Guidance on Applying the Risk Management Standard

Day 4: Risk Controls, Benefit-Risk, Usability, Software and Post-Market Feedback

- Risk Control Option Hierarchy: Inherent Safety, Protective Measures and Information for Safety
- Overall Residual Risk Evaluation and Benefit-Risk Analysis Record
- Usability Engineering Overview: Use Errors, User Interface Hazards and Summative Evaluation
- Software Hazard Analysis and Cybersecurity Risk for Connected Devices
- Post-Market Surveillance Plan, Complaint Trending, Vigilance Reporting and Field Safety Corrective Actions

Day 5: Case Study Workshop: Device Risk Management File

- Case Brief: Infusion Pump Adverse Event and Hospital Recall Execution
- Case Brief: Mobile Health App Reclassified as Software as a Medical Device
- Technical Documentation Index and Risk Traceability Matrix Build
- Risk Management Report Drafting and Production and Post-Production Information Loop
- Device Risk Management File Presentation to a Peer Review Panel

Skills You Will Gain:

- Device Risk Classification
- Design Control Documentation
- Hazard Analysis
- Failure Mode and Effects Analysis
- Residual Risk Justification
- Usability Risk Screening
- Post-Market Surveillance Planning
- Field Safety Corrective Action Handling

Why Attend This Course:

- Return with a Device Risk Management File for a product from your own portfolio, ready for internal review
- Link complaints, service reports and incident data to specific hazards so risk estimates are updated from evidence
- Handle recalls and field safety notices with defined roles for manufacturer, distributor and hospital teams
- Compare device risk practice with peers from manufacturing, distribution and hospital biomedical engineering

Conclusion:

Safe medical devices depend on a risk file that stays live from the first design input to the last unit in clinical use. The course moves from device classification and the ISO 13485 quality management system through the ISO 14971 process, risk controls, benefit-risk decisions, usability and software hazards, to post-market surveillance, vigilance and recalls. The final day turns this into a Device Risk Management File ready for review by quality, regulatory and clinical engineering leads.