ISO 13485 Certification Training: Master Medical Devices Quality Management System

20 – 24 September 2027
Dubai

AGILE LEADERS
Training Center

ISO 13485 Certification Training: Master Medical Devices Quality Management System

Ref: 103600269_84904 **Date:** 20 – 24 September 2027 **Location:** Dubai **Fees:** 6500 Euro

Overview

Medical device manufacturers face rigorous compliance requirements when managing product lifecycles and product safety. This ISO 13485 Certification Training provides technical guidance to establish, audit, and optimize a medical devices quality management system across design, production, and post-market surveillance. Participants examine quality manuals, device master records, risk assessments, and non-conformance workflows to prevent contamination, ensure traceability, and sustain regulatory alignment across operating lines. Technical teams complete the program equipped with internal audit checklists and CAPA verification frameworks. This course is delivered by Agile Leaders Training Center.

Who Should Attend

- Professionals responsible for establishing and maintaining quality management systems across medical device facilities.
- Engineers responsible for design controls, design history files, and risk management documentation.
- Specialists responsible for conducting internal quality audits and managing supplier qualification processes.
- Quality assurance managers responsible for corrective and preventive action investigation and documentation.
- Production leaders responsible for cleanroom environmental controls, process validation, and lot traceability.

Departments and Industries

This course serves quality assurance, technical compliance, and operations teams operating across the healthcare technology and life sciences sectors.

- Quality Assurance and Regulatory Compliance in In-Vitro Diagnostics Manufacturing
- Design and Process Engineering in Cardiovascular and Orthopaedic Implant Facilities
- Operations and Sterilisation Management in Single-Use Surgical Consumables Production
- Supplier Quality and Procurement in Medical Imaging Equipment Assembly
- Clinical Affairs and Post-Market Surveillance in Digital Health and Therapeutic Devices

Learning Objectives

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

- Apply ISO 13485:2016 clauses to build an audit-ready medical devices quality management system.
- Evaluate device design controls and risk analysis records using ISO 14971:2019 risk management matrices.
- Build corrective and preventive action procedures using root-cause analysis fishbone diagrams and 5-Why methods.
- Analyse production cleanliness protocols using ISO 14644 cleanroom environmental monitoring logs.
- Prioritise supplier qualification criteria using critical component risk rating matrices.
- Construct internal audit programmes using ISO 19011:2018 audit checklists and sampling plans.

Course Agenda

Day 1: Quality Management System Architecture and Governance

- Management Responsibility Frameworks using Quality Policy and Measurable Quality Objectives
- Medical Device Quality Manual Drafting using ISO 13485:2016 Clause Mapping Tables
- Medical Device File and Technical Documentation Structuring via ISO TR 20416 Guidelines
- Document Control Protocols using Engineering Change Order and Approval Workflows
- Resource Allocation Planning using Training Competency Matrices and Training Record Logs

Day 2: Risk Management and Product Realisation Controls

- Design Control Implementation using Design History Files and Design Review Minutes
- Risk Analysis Execution using ISO 14971:2019 Failure Mode and Effects Analysis Templates
- Design Verification and Validation Planning using Biocompatibility Testing Matrices
- Supplier Quality Agreement Design using Supplier Criticality Classification Frameworks
- Purchasing Verification Workflows using Incoming Material Inspection Checklists

Day 3: Manufacturing, Sterilisation, and Contamination Controls

- Production Process Validation Protocols using Installation, Operational, and Performance Qualification
- Cleanroom Environmental Monitoring using ISO 14644 Differential Pressure and Particle Logs
- Sterilisation Assurance Validation using ISO 11135 and ISO 11137 Dose Auditing Frameworks
- Product Identification and Traceability using Device Master Records and Lot Travellers
- Servicing and Installation Protocols using Field Technical Service Reporting Logs

Day 4: Measurement, Monitoring, and Corrective Actions

- Customer Feedback Evaluation using Post-Market Surveillance Reporting Logs
- Complaint Handling Workflows using Medical Device Vigilance Reporting Decision Trees
- Non-Conforming Product Control using Material Review Board Disposition Registers
- Root Cause Investigation Protocols using 8D Problem Solving and Fishbone Diagrams
- CAPA Effectiveness Verification using Statistical Trend Analysis and Process Capability Indices

Day 5: Internal Auditing and Management Review

- Audit Schedule Construction using ISO 19011:2018 Risk-Based Audit Programme Templates
- Internal Audit Checklist Development using Process Approach Audit Worksheets
- Objective Evidence Sampling using AQL Statistical Sampling Tables
- Non-Conformity Grading and Reporting using Finding Severity Classification Matrices
- Capstone Integrated Management Review Simulation and Action Plan Portfolio

Practical Exercises

Participants work through practical scenarios to develop technical quality documentation.

- Suggested activity: Draft a quality manual clause cross-reference matrix aligning device technical files with quality objectives.
- Suggested activity: Conduct a design failure mode analysis using an ISO 14971:2019 risk evaluation matrix.
- Suggested activity: Formulate a corrective action investigation plan using an 8D root-cause problem-solving worksheet.
- Suggested activity: Develop an internal audit non-conformity report using an ISO 19011:2018 finding classification sheet.

FAQs

What scope of devices does this training cover?

The syllabus addresses active medical devices, in-vitro diagnostics, sterile consumables, and surgical implants, focusing on core quality processes applicable across all medical equipment classifications.

How does risk management integrate into the course?

Risk management principles from ISO 14971:2019 are woven directly into design controls, supplier management, production cleanliness, and post-market complaint analysis throughout the modules.

Are internal audit methodologies practiced during the sessions?

Participants practice audit planning, checklist development, evidence collection, and non-conformity reporting based on ISO 19011:2018 auditing guidelines on the final day.

Does this course address process validation requirements?

Process validation workflows, including installation, operational, and performance qualification stages, are examined specifically for manufacturing, packaging, and sterilisation procedures.

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Conclusion

Participants return to their facilities prepared to direct quality management systems with systematic discipline. By deploying structured design controls, robust supplier evaluations, validated manufacturing processes, and rigorous internal audit workflows, technical professionals safeguard device reliability, protect end users, and maintain steady organizational alignment across every phase of the medical device lifecycle.