

ISO 13485:2016 Lead Auditor Training Program for Medical Devices with FDA QMSR & MDSAP Regulatory Requirements (USA/Canada) — 2026 Update



OEM: TÜV SÜD • Code: eg-46-43-26-0052

COURSE DESCRIPTION

Upon successful completion of this course and its examination, delegates will be able to: This intensive and participative Lead Auditor program uses case studies, workshops, role-plays, and group activities to build practical auditing capability and ensure learners can confidently perform and lead MD-QMS audits globally.

AUDIENCE PROFILE

- The ISO 13485 Lead Auditor certification training course can be attended by medical device quality testing professionals interested in conducting first-party, second-party, and third-party audits.
- Management representatives.
- Quality directors, managers, and engineers.
- Consultants.

PREREQUISITES

- As the ISO 13485 Lead Auditor training covers auditing concepts utilizing ISO 13485, a prior understanding of ISO 13485 and its implementation within a Medical Device business and internal audit experience is recommended.
- Other related standards
- Not sure which ISO 13485 training course you need?
- Progress from ISO 13485 fundamentals to advanced auditing expertise through this comprehensive medical device quality management learning pathway.
- !Medical Device Quality Management Learning Pathway
- Participants begin with an introduction to ISO 13485 and FDA QMSR requirements in the ISO 13485 Quality Management Systems for Medical Device Manufacturers with FDA QMSR (USA/Canada) — 2026 Update \[eg-46-11-26-0019\] training course, gaining a clear understanding of the regulatory and quality management expectations for medical device manufacturers.
- They then advance to implementation techniques with the ISO 13485:2016 – Introduction & Implementation with FDA QMSR (USA/Canada) — 2026 Update \[eg-46-43-26-0001\] training course, learning how to establish, maintain, and improve a compliant Quality Management System that supports product quality, patient safety, and regulatory readiness.
- Once a strong implementation foundation has been established, learners develop practical auditing competencies through the ISO 13485:2016 Internal Auditor \[eg-46-43-26-0051\] course, where they learn to assess QMS effectiveness and drive continual improvement.

- This pathway culminates with the ISO 13485:2016 Lead Auditor Training Program for Medical Devices with FDA QMSR & MDSAP Regulatory Requirements (USA/Canada) — 2026 Update [eg-46-43-26-0052], providing the advanced audit leadership skills needed to conduct and lead audits against ISO 13485, FDA QMSR, and MDSAP requirements. This structured progression is ideal for quality professionals, regulatory specialists, implementation teams, internal auditors, and future lead auditors seeking a complete development path from compliance awareness to auditing excellence.
- MD -QMS Terms and definitions
- MD -QMS Requirements
- ISO 9000 – Terms and Definitions
- IEC 62304
- PD ISO/TR 80002-2-2017
- IEC/ISO60601
- ISO14937
- ISO14644
- 14698-1
- GHTF
- IMDRF
- MDSAP

COURSE OBJECTIVES

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

- Develop the competence to plan, conduct, report, and follow up on first-, second-, and third-party audits of Medical Device Quality Management Systems (MD-QMS) in accordance with ISO 13485:2016 and internationally recognized auditing principles.
- Gain a thorough understanding of ISO 13485:2016 requirements and their practical application, enabling effective assessment of quality management systems across the medical device lifecycle.
- Strengthen auditing skills using ISO 19011 and ISO/IEC 17021 guidelines, improving the ability to evaluate conformity, identify nonconformities, and drive continual improvement.
- Understand the latest FDA Quality Management System Regulation (QMSR) requirements and how FDA's alignment with ISO 13485:2016 impacts audit planning, execution, documentation, and reporting.
- Gain valuable insight into Canadian CMDR and MDSAP requirements, allowing auditors to assess compliance for organizations operating in both the U.S. and Canadian medical device markets.
- Learn how to audit risk-based quality management processes, including design and development controls, supplier management, production controls, complaint handling, post-market surveillance, and vigilance activities.
- Enhance knowledge of regulatory documentation and traceability requirements, including Medical Device Files (MDF), UDI requirements, lifecycle records, and post-market compliance obligations.
- Build confidence in evaluating regulatory compliance and audit readiness, helping organizations prepare for certification, regulatory inspections, and customer audits.
- Improve the ability to identify risks, gaps, and opportunities for improvement, contributing to stronger quality systems, product safety, and regulatory compliance.
- Benefit from expert instruction and an Exemplar Global-certified training program, providing industry-recognized auditor training and professional development.
- Enhance professional credibility and career growth opportunities by acquiring advanced lead auditor competencies that are highly valued within quality assurance, regulatory affairs, supplier quality, and compliance functions.

COURSE OUTLINE

Module 1

1) MD-QMS Introduction and Process Approach

- Purpose and benefits of MD-QMS-Requirements for Regulatory Purposes including understanding of the basic MD-QMS principles
- Terms, Fundamentals and Principles
- Process Approach with PDCA
- Mandatory documents for regulatory purposes
- Difference between compliance and conformance
- Relationship between IMDRF and GHTF
- Principles of IMDRF
- MDR European Union Regulations
- MD-QMS Requirements (Clause 1 to 8)

1.5) ISO 13485 with FDA QMSR (USA/Canada) 2026 Update — NEW MODULE

- FDA modernization of 21 CFR 820 into QMSR (effective Feb 2, 2026)
- ISO 13485 incorporation and remaining FDA-specific requirements (UDI 830, MDR 803, C&R 806, Tracking 821)
- Transition to the Medical Device File (MDF) replacing DMR/DHF/DHR
- North America regulatory comparison: FDA QMSR vs CMDR/MDSAP — audit implications
- Canadian licensing (MDL / MDEL), bilingual labeling, PMS/incident reporting, and MDSAP audit expectations
- Internal audit considerations under QMSR & MDSAP
- Traceability expectations under design (7.3) and production (7.5.8/7.5.9) controls

2) Auditing Principle

- Auditing objectives
- Types of audits
- Audit life cycle
- Terms and Definition
- Principle of Auditing
- Annex A – Guidance of Auditors

3) Role and Responsibilities of Auditor

- Audit Programme objectives
- The auditees responsibilities
- The lead auditors' responsibilities
- Auditors qualification and certifications

4) Role Planning an Audit

- Pre-Audit planning
- Reviewing documentation
- Developing an audit plan
- Preparing checklists or working documents
- Communication factors

5) Conducting an Audit

- Opening meeting
- Collecting objective/audit evidence
- Effective interviewing techniques
- Identifying and recording nonconformities
- Preparing for the closing meeting

6) Reporting Audit Results

- Conducting the closing meeting
- Preparing the audit report
- Distributing the audit report

7) Corrective Actions

- Corrective action responsibilities
- Follow up scheduling
- Monitoring corrective action

8) ISO 13485: 2016 Registration

- The registration processes
- Surveillance audits
- 9) Exercises/ Role play (50 % of course Time)
- 10) Written Examination

DELIVERY NOTE

- Course delivered by one of TÜV SÜD's leading industry experts
- Small class sizes enhance trainer-delegate relationship
- Receive globally recognised TÜV SÜD certificate upon completion