COURSE TABLE OF CONTENTS

ISO 13485:2016 – Introduction & Implementation with FDA QMSR (USA/Canada) — 2026 Update

OEM: TÜV SÜD • Code: eg-46-43-26-0001

COURSE DESCRIPTION

The program is designed for professionals who wish to gain a solid understanding of the fundamental requirements of ISO 13485:2016 and explore practical approaches for implementing the standard within their organization. ISO 13485:2016 serves as the cornerstone of quality management systems for the medical device industry and its supply chain. The standard outlines essential requirements for manufacturers, emphasizing the importance of comprehensive process-based risk management. These risk-management activities must be integrated across all quality-related processes, including those performed by external suppliers. Beyond product development and manufacturing, ISO 13485:2016 also requires organizations to address processes that occur after medical devices are placed on the market, ensuring ongoing safety, effectiveness, and regulatory compliance throughout the product lifecycle. At the end of this course, participants will be able to:

AUDIENCE PROFILE

- This training is ideal for:
- Medical device manufacturers, suppliers, and service providers
- Quality Management Officers (QMOs), Quality Engineers, Regulatory Affairs professionals
- Product Managers, R&D, operations, and compliance teams
- Consultants supporting ISO 13485, QMSR transition, CMDR/MDSAP compliance
- Organizations preparing for ISO 13485 certification or updating their QMS for QMSR 2026

PREREQUISITES

- There are no formal prerequisites.
- 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.

COURSE OBJECTIVES

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

- Learn how to successfully implement or enhance a Quality Management System (QMS) based on ISO 13485:2016, ensuring alignment with industry best practices and regulatory expectations for medical device manufacturers.
- Benefit from expert-led interpretation of ISO 13485:2016 requirements, gaining practical insights into how the standard can be effectively applied within real-world business environments.
- Build a strong foundation in the structure, intent, and key requirements of ISO 13485:2016, enabling a clear understanding of quality management principles across the medical device lifecycle.
- Understand how to integrate quality and risk management into organizational processes, supporting consistent product quality, regulatory compliance, and continuous improvement initiatives.
- Gain practical experience through implementation workshops and hands-on exercises, helping translate ISO 13485 requirements into day-to-day operational processes.
- Stay current with regulatory changes in North America, including FDA Quality Management System Regulation (QMSR), Canadian Medical Devices Regulations (CMDR), and MDSAP requirements.
- Develop the ability to map ISO 13485 requirements to existing business workflows, facilitating smoother implementation and improved organizational efficiency.
- Strengthen competence in risk-based thinking, traceability, auditing, and lifecycle management, ensuring compliance throughout product development, manufacturing, and post-market activities.
- Prepare for FDA and Health Canada expectations, including audit readiness, documentation requirements, and regulatory oversight activities.
- Enhance professional credibility and career opportunities through training provided by TÜV SÜD experts and supported by Exemplar Global accreditation.
- Receive a globally recognized TÜV SÜD certificate of participation, demonstrating your commitment to quality management excellence and regulatory compliance in the medical device industry.

COURSE OUTLINE

Module 1: Regulatory & Normative Foundations

- ISO 13485:2016 structure & intent
- Global regulatory landscape (EU MDR overview, U.S. QMSR, Canada CMDR/MDSAP)
- Lifecycle of a medical device

Module 2: U.S. QMSR (21 CFR 820) — Effective February 2, 2026

- Alignment with ISO 13485:2016
- FDA-specific retained requirements (UDI, MDR, C&R, Tracking)
- MDF vs legacy DHF/DMR/DHR

- FDA inspection posture: MR / Internal Audits / Supplier Audits

Module 3: Canada — CMDR & MDSAP Essentials

- Licensing pathways (MDEL, MDL, MDSAP)
- Labeling & bilingual requirements
- PMS, incident reporting, recalls, summary reports
- Health Canada expectations for audits

Module 4: ISO 13485:2016 in Detail

- Quality management system structure
- Documentation requirements & the MDF
- Design & development controls
- Purchasing & supplier management
- Production & process controls
- Cleanliness, installation, servicing, sterilization
- Monitoring, measurement & improvement

Module 5: Risk Management (ISO 14971)

- Risk analysis
- Risk control mapping
- Integration into design, production & PMS

Module 6: Hands-On Implementation Workshop

- Process mapping
- Practical exercises

DELIVERY NOTE

- Live instructor-led virtual classroom
- Real-time Q&A, examples, case studies
- Group discussions & problem-solving
- Quizzes and applied learning
- 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