KOENIG SOLUTIONS · COURSE OUTLINE

ISO 13485 Quality Management Systems for Medical Device Manufacturers with FDA QMSR (USA/Canada) — 2026 Update

1 Day	1	21	eg-46-11-26-0019
DURATION	MODULES	TOPICS	COURSE CODE

COURSE OVERVIEW

Boost your company's quality and safety by mastering the implementation of management systems in the medical device industry. Our 1-day training course on Management Systems for Medical Device Manufacturers according to ISO 13485 is designed to help you effectively transfer the requirements of applicable standards to your organization. One of the key challenges in introducing an effective management system is understanding and applying the requirements of ISO 13485:2016, which has a process-oriented structure. This seminar will guide you through the standard's requirements and help you implement them sensibly in your company. You will learn what to look out for when introducing or adapting the management system and understand the success factors, and you will acquire the necessary knowledge to install a management system as a manufacturer of medical devices or as a supplier in the medical device industry. The training will cover special focal points of ISO 13485:2016, including: Risk Management Change Management Software Validation Extended Requirements for Development and Market Monitoring These aspects are becoming increasingly important! By the end of the training, participants will be able to: Master ISO 13485:2016 Requirements Understand the structure, clauses, and intent of ISO 13485:2016 and how to apply them effectively in your organization. Identify key differences between ISO 13485 and ISO 9001:2015 (documentation, risk, regulatory orientation, process controls). Implement a Regulatory-Compliant QMS Integrate applicable regulatory requirements into the QMS, including MDR/IVDR, QMSR, CMDR/MDSAP. Understand organizational regulatory roles (manufacturer, AR, importer, distributor) and expectations under global frameworks. Strengthen Risk-Based Processes Apply risk-based thinking to QMS processes (clauses 4–8). Understand the relationship between ISO 13485, ISO 14971, and regulatory expectations. Control the Full Product Lifecycle Understand design and development planning, inputs, outputs, reviews, verification & validation (V&V), and change control requirements. Implement bidirectional design traceability from inputs -> outputs -> V&V -> risk controls. Manage production controls, cleanliness, contamination control, identification & traceability, UDI, and servicing. Apply Validation Requirements Learn when to use IQ/OQ/PQ for process validation. Validate QMS software, production software, and measurement software according to ISO/TR 80002-2 & GAMP5 principles. Ensure Market Safety Through PMS Implement complaint handling, vigilance reporting, trend analysis, and PMS systems aligned with regulatory expectations (8.2.1–8.2.3). This

course is taught by TÜV SÜD's industry experts and is certified by Exemplar Global. Join us for this essential 1-day training course to enhance your understanding of ISO 13485:2016 and ensure your organization meets the highest standards of quality and safety. Enroll today and take the first step towards implementing a robust management system for medical devices!

WHO THIS COURSE IS FOR

- This course is ideal for experts and executive personnel of medical device manufacturers and their suppliers that are involved in quality management system introduction, establishment and maintenance in the area of medical devices. And for all professionals in the manufacturing and supply of medical devices who want to gain a basic understanding of management systems and regulatory requirements, including:
- Quality Assurance Managers
- Regulatory Affairs Specialists
- Compliance Officers
- Design & Development Engineers
- Production & Operation Managers
- Supplier Quality Engineers
- Medical Device Manufacturers & Contract Manufacturers

PREREQUISITES

- There are no formal prerequisites for this training course.

LEARNING OBJECTIVES

What You Will Learn

- Understand ISO 13485:2016: Gain knowledge of the process-oriented standard for management systems in the medical device industry.
- Implement ISO 13485:2016: Ensure meaningful implementation of the standard in your company.
- Optimize Processes: Improve your processes during the introduction of a management system.
- Stay Updated: Get an overview of the current state of standardization and international regulatory requirements.
- Learn Documentation Requirements: Understand the documentation requirements and differences from ISO 9001:2015.

COURSE SYLLABUS

1 Module, 21 Topics

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Topics Covered

TOPICS

- Course Topics at a Glance

1\. Foundations of ISO 13485:2016

- Structure, purpose, and regulatory alignment
- Process approach and risk-based thinking
- Mandatory documentation & records; the Medical Device File (MDF)

2\. ISO 13485 and Global Regulations

- MDR/IVDR Annex Z mapping
- FDA QMSR: ISO 13485 alignment & remaining U.S.-specific requirements
- CMDR & MDSAP expectations for Canadian market access
- QMS roles under MDR/IVDR and international frameworks

3\. Product Lifecycle Controls

- Design & development (V-Model, waterfall model, design transfer)
- Verification, validation, usability, clinical/performance evaluation
- Production controls, cleanliness, installation, servicing

4\. Validation Requirements

- Process validation (IQ, OQ, PQ)
- Software validation for QMS tools, production systems, and monitoring software
- Test method validation, equipment qualification

5\. Change Management

- Engineering change control
- Product & QMS changes
- Regulatory reporting thresholds
- Impact analysis across design, production, software, risk, suppliers

6\. Post-Market Surveillance

- Feedback, complaints, vigilance, reporting to authorities
- Data analysis & CAPA
- PMS as an input to risk management and design changes

DELIVERY NOTE

How It Is Delivered

- Instructor-led in a virtual classroom
- Course delivered by one of TÜV SÜD's leading industry experts
- Small class sizes enhance trainer-delegate relationship
- Receive globally recognized TÜV SÜD certificate upon completion

WHAT IS INCLUDED

Everything You Need to Succeed

- Koenig course material for every module
- Delivery by certified instructors and subject matter experts
- Hands-on exercises throughout the course
- Course completion certificate from Koenig

ABOUT KOENIG

Who We Are

Established in 1993, Koenig Solutions is a globally recognised training provider with 35+ technology partnerships, 5,000+ training programmes and a network of certified instructors and subject matter experts, supporting individuals and enterprise teams worldwide.

FLEXIBLE DELIVERY

Learn the Way That Suits You

Classroom Training | Live Online Classes (ILO) | Fly-Me-A-Trainer (FMAT) | Flexi (Self-Paced) | 1-on-1 Training

Ready to Get Started?

Talk to a learning advisor about schedules, group training and customised delivery.

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