Medical Device Regulatory Affairs (ISO 13485) Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

A course on Medical Device Regulatory Affairs (ISO 13485) is crucial for professionals in the medical technology sector. It provides an in-depth understanding of the **ISO 13485:2016** standard, which is the internationally recognized benchmark for a quality management system (QMS) specific to medical devices. Medical Device Regulatory Affairs (ISO 13485) Training Course is essential for ensuring product safety and efficacy throughout the entire lifecycle, from design and development to post-market surveillance. It empowers individuals and organizations to navigate complex global regulatory landscapes, including those of the **European Union (EU MDR)** and the **U.S. Food and Drug Administration (FDA)**, enabling them to achieve and maintain compliance, streamline market access, and reduce business risk.

This comprehensive program focuses on practical application and real-world scenarios, moving beyond theoretical knowledge. Participants will learn how to **implement**, **maintain**, and **audit** a compliant QMS. The curriculum covers key areas such as **risk management**, **technical documentation**, and **corrective and preventive actions (CAPA)**. By mastering these competencies, professionals can not only ensure their organizations meet stringent regulatory requirements but also contribute to a culture of quality, ultimately bringing safe and effective medical devices to market faster and more efficiently.

Programme Curriculum

Medical Device Regulatory Affairs (ISO 13485) Training Course

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Course Objectives

1. Master the principles and requirements of ISO 13485:2016.
2. Navigate the complexities of EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).
3. Understand the U.S. FDA 21 CFR Part 820 and its alignment with ISO 13485.
4. Develop and implement a robust Quality Management System (QMS) for medical devices.
5. Apply risk-based thinking and ISO 14971 for effective risk management.
6. Prepare comprehensive technical documentation and a design dossier.
7. Conduct effective internal audits and prepare for regulatory inspections.
8. Implement a system for Corrective and Preventive Actions (CAPA).
9. Manage post-market surveillance (PMS) and vigilance reporting.
10. Ensure traceability and Unique Device Identification (UDI) compliance.
11. Understand the role of clinical evaluation and performance studies.
12. Integrate digital health and software as a medical device (SaMD) into a compliant QMS.
13. Leverage artificial intelligence (AI) in medical device development and regulation.

Target Audience

1. Regulatory Affairs Professionals
2. Quality Assurance/Quality Control Engineers & Managers
3. R&D and Product Development Engineers
4. Internal & External Auditors
5. Senior Management & Executives
6. Clinical Affairs Specialists
7. Supply Chain and Operations Managers
8. Consultants specializing in medical devices

Course Modules

Module 1: Introduction to Medical Device Regulatory Landscape

- Overview of the global regulatory framework for medical devices.
- The critical role of ISO 13485 in achieving global market access.
- Understanding the hierarchy of regulatory documents and standards.
- Key definitions: medical device, intended use, and lifecycle.
- Introduction to international bodies like the International Medical Device Regulators Forum (IMDRF).
- **Case Study:** A small, innovative start-up developing a novel diagnostic device needs to decide on its first target market.

Module 2: The Core of ISO 13485:2016

- Detailed breakdown of the standard's clauses and their requirements.
- The differences between ISO 13485:2016 and its predecessor, ISO 13485:2003.
- The relationship between ISO 13485 and ISO 9001.
- Key principles: risk management, regulatory compliance, and customer focus.
- Practical steps for establishing an ISO 13485 compliant QMS.
- **Case studies**: Implementing ISO 13485:2016 at MedTech Diagnostics Ltd

Module 3: Management Responsibility and Quality Policy

- Understanding leadership's role in driving quality and compliance.
- How to create an effective and meaningful quality policy
- Defining roles, responsibilities, and authorities within the QMS.
- The importance of management review and its inputs and outputs.
- Ensuring resource availability for QMS effectiveness.
- **Case Study:** A medical device company fails a regulatory inspection due to a lack of management commitment.

Module 4: Resource Management

- Competence, training, and awareness for personnel.
- Infrastructure requirements for medical device manufacturing.
- Managing the work environment and contamination control.
- Planning and implementing a training matrix.
- Auditing resource management processes.
- **Case Studies**: Optimizing Resource Management in Pharmaceuticals Systems

Module 5: Product Realization: Planning and Design

- Overview of the product realization process.
- QMS planning and aligning with product requirements.
- Design and development planning and its critical inputs.
- Design and development reviews and verification activities.
- Design validation and design transfer.
- **Case Study:** An R&D team at a large medical device firm is developing a new surgical tool.

Module 6: Risk Management (ISO 14971)

- Understanding the principles of ISO 14971.
- Performing a risk analysis and risk evaluation.
- Identifying and mitigating risks throughout the product lifecycle.
- Creating a risk management file (RMF).

- Post-market risk monitoring and vigilance.
- **Case Study:** Risk Management in the Development of a Smart Insulin Delivery Pen

Module 7: Purchasing and Supplier Management

- Establishing criteria for evaluating and selecting suppliers.
- The importance of supplier agreements and quality clauses.
- Managing purchased products and services.
- Supplier audits and monitoring performance.
- How to handle non-conforming purchased goods.
- **Case Study:** A company discovers that a critical component from a third-party supplier is defective, leading to a product recall.

Module 8: Production and Service Controls

- Validating processes for production and service provision.
- Implementing cleanliness controls and sterilization procedures.
- Installation and servicing activities.
- Managing labeling and packaging.
- Traceability and identification of medical devices.
- **Case Study:** Ensuring Quality and Efficiency in Production

Module 9: Control of Monitoring and Measuring Equipment

- Ensuring the accuracy and reliability of all measuring equipment.
- Calibration and maintenance schedules.
- Documenting calibration records.
- What to do when equipment is found to be out of calibration.
- Auditing the calibration process.
- **Case Study:** A quality control department finds that its primary measurement tool has been providing inaccurate readings for months.

Module 10: Non-Conforming Product and CAPA

- Procedures for handling non-conforming products.
- The process of Corrective and Preventive Actions (CAPA).
- Distinguishing between correction, corrective action, and preventive action.
- Conducting a thorough root cause analysis.
- Documenting and closing out CAPA records.
- **Case Study:** Handling a Non-Conforming Product and Implementing CAPA

Module 11: Internal Audits and Management Reviews

- Planning and conducting effective internal audits.
- Auditor competence and independence.
- Reporting audit findings and managing non-conformities.
- The role of the Management Review in continuous improvement.
- Preparing for a third-party certification audit.
- **Case Study:** We'll examine a medical device company's preparations for its annual ISO 13485 surveillance audit.

Module 12: Post-Market Surveillance (PMS)

- Requirements for Post-Market Surveillance (PMS).
- Systematic collection and analysis of post-market data.
- Vigilance reporting and handling of adverse events.
- The relationship between PMS and risk management.
- Proactive post-market clinical follow-up (PMCF).
- **Case Study:** Post-Market Surveillance of the CardioSense Implant

Module 13: The EU MDR and IVDR

- Key changes and requirements introduced by the EU MDR and IVDR.
- Understanding the Conformity Assessment Procedures.
- The role of the Notified Body.
- Navigating the EUDAMED database.
- Clinical evaluation and the Clinical Evaluation Report (CER).
- **Case Study:** A manufacturer of a Class IIa device struggles to transition to the new **EU MDR**.

Module 14: U.S. FDA Regulations

- Overview of the FDA regulatory framework.
- Understanding 21 CFR Part 820 Quality System Regulation (QSR).
- The 510(k), PMA, and De Novo regulatory pathways.
- Handling and reporting Medical Device Reports (MDRs).
- The Medical Device Single Audit Program (MDSAP).
- **Case Study**: Approval and Regulation of a New Diabetes Drug

Module 15: Auditing and Regulatory Inspections

- Preparing for and managing a regulatory inspection.
- Understanding the audit process, from opening to closing meetings.
- Techniques for responding to auditor questions.
- Handling and responding to audit findings and Form 483s.
- Ensuring a successful outcome and continuous improvement.
- **Case Study:** A medical device company receives a **Form 483** from the FDA after a routine inspection.

Training Methodology

- **Interactive Lectures:** Led by experienced industry professionals with real-world expertise.
- **Case Studies:** In-depth analysis of real-world scenarios to illustrate concepts.
- **Group Discussions:** Fostering collaborative problem-solving and knowledge sharing.
- **Practical Exercises:** Hands-on activities for **QMS documentation** and **risk analysis**.
- **Q&A Sessions:** Opportunities for direct interaction with instructors.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call *+254769199797*

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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