ISO 13485:2016 Medical Devices Quality Management Training Course

Professional Development Training Course Outline

Category	Quality Assurance and ISO standards	**Duration**	10 Days
Base Fee	$3,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

ISO 13485:2016 Medical Devices Quality Management Training Course is designed to equip professionals, organizations, and regulatory bodies with in-depth knowledge of international standards governing medical devices. This course focuses on building compliance strategies, strengthening product safety, and ensuring regulatory alignment across global healthcare markets. Participants will gain a clear understanding of risk management, process validation, documentation control, and post-market surveillance, all of which are essential components of the ISO 13485:2016 standard. Through this training, learners will be prepared to meet industry requirements while driving efficiency and quality excellence within medical device organizations.

This training program integrates practical applications, case studies, and real-world examples, enabling participants to develop skills that are immediately transferable to their professional environments. With an emphasis on regulatory updates, quality assurance systems, and internal auditing practices, the course ensures that attendees are equipped to handle evolving compliance challenges. By the end of the program, participants will not only understand the requirements of ISO 13485:2016 but also master effective implementation strategies that enhance organizational performance and product reliability.

Programme Curriculum

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Course Objectives

1. Understand the core principles and structure of ISO 13485:2016.
2. Learn effective documentation and record management systems.
3. Apply risk management practices specific to medical devices.
4. Gain knowledge on product lifecycle and regulatory compliance.
5. Enhance skills in internal quality auditing processes.
6. Master corrective and preventive actions (CAPA).
7. Implement supplier quality management strategies.
8. Strengthen product safety and traceability systems.
9. Integrate post-market surveillance for continuous improvement.
10. Understand regulatory harmonization across global markets.
11. Develop process validation and verification competencies.
12. Improve leadership and organizational commitment to quality.
13. Build sustainable quality culture within medical device organizations.

Organizational Benefits

1. Improved compliance with international regulatory requirements.
2. Enhanced product safety and reliability.
3. Stronger global market access for medical devices.
4. Increased efficiency through streamlined processes.
5. Reduced risks associated with non-conformities.
6. Improved customer confidence and satisfaction.
7. Better supplier and stakeholder relationship management.
8. Enhanced organizational reputation in global healthcare.
9. Reduced costs through effective CAPA implementation.
10. Long-term sustainability of quality management systems.

Target Audiences

1. Quality assurance managers and officers.
2. Regulatory affairs professionals.
3. Internal auditors for medical device companies.
4. Research and development specialists.
5. Production and operations managers.
6. Healthcare compliance officers.
7. Senior management and leadership teams.

8. Consultants in the medical device sector.

Course Duration: 10 days

Course Modules

Module 1: Introduction to ISO 13485:2016

- Overview of medical device quality management systems
- Key differences between ISO 13485:2016 and previous versions
- Understanding clauses and requirements
- Importance of regulatory compliance in global healthcare
- Case study: Transition challenges in ISO 13485 implementation
- Role of ISO 13485 in organizational quality improvement

Module 2: Documentation and Record Management

- Structure of documented information
- Best practices for document control
- Record retention requirements
- Procedures for change management
- Case study: Document control in medical device audits
- Benefits of effective documentation practices

Module 3: Risk Management in Medical Devices

- Risk assessment methodologies (FMEA, HACCP)
- Identifying potential hazards in product lifecycle
- Risk control and mitigation strategies
- Role of ISO 14971 in supporting ISO 13485
- Case study: Risk management in implantable devices
- Integrating risk management into QMS

Module 4: Regulatory Framework and Compliance

- Global regulatory requirements (FDA, EU MDR)
- Harmonization of standards across regions
- Role of notified bodies and certification audits
- Impact of non-compliance on business continuity
- Case study: Regulatory non-compliance consequences
- Building a proactive compliance strategy

Module 5: Internal Auditing Principles

- Importance of internal audits in QMS
- Planning and conducting effective audits
- Reporting and follow-up procedures
- Competency of internal auditors
- Case study: Internal audit findings in device manufacturing
- Tools and techniques for successful auditing

Module 6: Corrective and Preventive Actions (CAPA)

- Identifying root causes of non-conformities
- Implementing corrective actions
- Preventive measures for future risks
- Monitoring and measuring CAPA effectiveness
- Case study: CAPA in catheter manufacturing
- Common CAPA challenges and solutions

Module 7: Supplier Quality Management

- Supplier evaluation and selection
- Monitoring supplier performance
- Managing supplier non-conformities
- Collaboration with suppliers for quality improvement
- Case study: Supplier management in disposable devices
- Benefits of strong supplier relationships

Module 8: Product Safety and Traceability

- Ensuring product safety through design controls
- Importance of traceability in recalls
- Batch and lot control mechanisms
- Patient safety considerations
- Case study: Traceability in cardiac devices
- Building robust traceability systems

Module 9: Post-Market Surveillance

- Monitoring product performance after launch
- Complaint handling and reporting
- Feedback integration into QMS
- Role of vigilance systems in healthcare safety
- Case study: Post-market surveillance in orthopedic devices
- Continuous improvement through surveillance

Module 10: Process Validation and Verification

- Understanding validation requirements
- Verification vs. validation differences
- Tools for process validation
- Regulatory expectations in validation
- Case study: Validation in sterilization processes
- Importance of continuous process monitoring

Module 11: Design and Development Controls

- Planning design and development processes
- Design review, verification, and validation
- Role of cross-functional teams
- Managing design changes effectively
- Case study: Design control in diagnostic devices
- Ensuring compliance through design documentation

Module 12: Leadership and Management Commitment

- Role of leadership in QMS success
- Establishing quality policy and objectives
- Building a quality culture
- Employee engagement in quality improvement
- Case study: Leadership role in ISO 13485 certification
- Long-term impact of management commitment

Module 13: Customer and Stakeholder Engagement

- Identifying customer requirements
- Effective communication strategies
- Complaint management and resolution
- Role of stakeholders in QMS success
- Case study: Stakeholder engagement in device recalls
- Building trust through transparency

Module 14: Continuous Improvement Strategies

- Tools for continuous improvement (Kaizen, Six Sigma)
- Monitoring performance indicators
- Benchmarking best practices
- Innovation in quality systems
- Case study: Continuous improvement in device packaging
- Sustaining improvement initiatives

Module 15: Preparing for ISO 13485 Certification Audit

- Pre-audit preparation steps
- Understanding certification body expectations
- Managing audit interviews and evidence
- Addressing non-conformities effectively
- Case study: Certification audit readiness in SMEs
- Post-audit improvement planning

Training Methodology

- Instructor-led interactive sessions
- Group discussions and brainstorming
- Real-world case study analysis
- Practical workshops and exercises
- Mock audits and role-playing scenarios
- Digital resources and reading materials

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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