Medical Device ISO 13485 Regulatory Compliance Training Course

26 - 30 Oct 2026

Tokyo

5800 € (Per Person)

Ref: #ISO4980_116509

Course Introduction / Overview:

This comprehensive training course provides an in-depth exploration of the ISO 13485:2016 standard, the internationally recognized framework for a Quality Management System (QMS) in the medical device industry. In a sector where patient safety and product efficacy are paramount, a robust QMS is not just a regulatory necessity but a cornerstone of business success. This program, offered by BIG BEN Training Center, is meticulously designed to guide participants through every clause of the standard, translating complex requirements into practical, actionable steps. We will delve into the critical interplay between ISO 13485 and major global regulatory frameworks, including the EU Medical Device Regulation (MDR) and the FDA's Quality System Regulation (QSR) 21 CFR Part 820. As discussed by experts like Dr. Elemir E. Simko in publications such as "Medical Devices: A Practical Guide," the integration of quality and regulatory strategy is essential. This course moves beyond mere theory, focusing on real-world implementation, risk management based on ISO 14971, and the development of a quality culture that supports continuous improvement and sustained compliance, ensuring your organization is prepared for the rigors of regulatory audits and market demands.

Target Audience / This training course is suitable for:

- Quality Assurance Managers and Personnel.
- Regulatory Affairs Specialists and Associates.
- Medical Device Design and Development Engineers.
- Manufacturing and Production Managers.
- Internal and External Auditors.
- Clinical Affairs Professionals.
- R&D Managers and Scientists.
- Supply Chain and Purchasing Managers involved with medical device components.
- Consultants in the medical device industry.
- Top Management and Executives responsible for quality.

Target Sectors and Industries:

- Medical Device Manufacturing.
- In-Vitro Diagnostic (IVD) Device Manufacturing.
- Pharmaceutical companies with combination products.
- Contract Manufacturing Organizations (CMOs) for medical devices.
- Suppliers of components, materials, and services to the medical device industry.
- Medical device software development companies.
- Biotechnology and life sciences organizations.
- Governmental regulatory agencies and notified bodies.
- Testing and calibration laboratories serving the medical device sector.

Target Organizations Departments:

- Quality Assurance and Quality Control.
- Regulatory Affairs.
- Research and Development (R&D).
- Manufacturing and Production.
- Engineering.
- Clinical and Medical Affairs.
- Supply Chain Management and Procurement.
- Legal and Compliance.
- Post-Market Surveillance and Vigilance.

Course Offerings:

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

- Interpret the requirements of ISO 13485:2016 clause by clause.
- Develop, implement, and maintain a compliant Quality Management System (QMS).
- Integrate the principles of risk management according to ISO 14971 into the QMS.
- Understand the relationship between ISO 13485 and key global regulations like EU MDR and FDA QSR.
- Plan and conduct effective internal audits of a medical device QMS.
- Master the Corrective and Preventive Action (CAPA) process for continual improvement.
- Manage design and development controls for new medical devices effectively.
- Establish robust processes for production, service provision, and supplier control.
- Prepare technical documentation required for regulatory submissions.
- Lead their organization in preparation for successful third-party certification audits.

Course Methodology:

The training methodology at BIG BEN Training Center is designed to be immersive, interactive, and highly practical, ensuring that participants gain not only knowledge but also the skills to apply it effectively in their workplace. We move beyond traditional lectures by incorporating a dynamic blend of learning techniques. The course is built upon a foundation of expert-led presentations that break down the complex clauses of ISO 13485 and related regulations into understandable segments. These sessions are complemented by interactive group discussions and workshops, allowing participants to share experiences and solve problems collaboratively. A significant portion of the training is dedicated to real-world case studies, analyzing actual audit findings, product recalls, and compliance challenges faced by medical device companies. Participants will engage in hands-on exercises, such as drafting a risk management file, developing a CAPA plan, and outlining an internal audit checklist. This active learning approach, combined with continuous Q&A sessions and personalized feedback from our experienced instructors, ensures a comprehensive understanding and fosters the confidence needed to manage a medical device QMS effectively and drive a culture of quality within their organizations.

Course Agenda (Course Units):

Unit One Foundations of Medical Device Quality Management

- Introduction to ISO 13485:2016 and its structure.
- Key terminology and definitions in the medical device industry.
- The process approach and risk-based thinking.
- Relationship between ISO 13485, ISO 9001, and regulatory requirements.
- Overview of global regulatory frameworks (EU MDR, FDA QSR).
- The role of the Quality Management System (QMS) in the product lifecycle.
- Documenting the QMS: Quality Manual and required procedures.

Unit Two Management, Resources, and Planning

- Management responsibility and commitment.
- Establishing and communicating the Quality Policy.
- Defining quality objectives and planning to achieve them.
- Roles, responsibilities, and authorities within the QMS.
- Conducting effective management reviews.
- Resource management: human resources, infrastructure, and work environment.
- Competence, awareness, and training requirements for personnel.

Unit Three Product Realization and Design Controls

- Planning of product realization processes.
- Customer-related processes and communication.
- Design and development planning and inputs.
- Design and development outputs, review, verification, and validation.
- Controlling design and development changes and managing the design history file (DHF).
- Purchasing process, supplier evaluation, and verification of purchased product.
- Production and service provision controls, including process validation.

Unit Four Production Controls and Monitoring

- Control of production and service provision.
- Cleanliness of product and contamination control.
- Installation, servicing activities, and sterilization processes.
- Validation of processes for production and service provision.
- Identification and traceability requirements.
- Customer property and preservation of product.
- Control of monitoring and measuring equipment and calibration.

Unit Five Measurement, Analysis, and Improvement

- General requirements for monitoring and measurement.
- Feedback, complaint handling, and reporting to regulatory authorities.
- Planning and conducting internal audits.
- Monitoring and measurement of processes and product.
- Control of nonconforming product from detection to disposition.
- Analysis of data to demonstrate QMS suitability and effectiveness.
- The Corrective and Preventive Action (CAPA) process for continual improvement.

FAQ:

Qualifications required for registering to this course?

There are no requirements.

How long is each daily session, and what is the total number of training hours for the course?

This training course spans five days, with daily sessions ranging between 4 to 5 hours, including breaks and interactive activities, bringing the total duration to 20 - 25 training hours.

Something to think about:

How can a robust ISO 13485 QMS be leveraged not just as a compliance tool, but as a strategic driver for innovation and competitive advantage in the medical device industry?

What unique qualities does this course offer compared to other courses?

This course distinguishes itself by moving beyond a simple clause-by-clause review of the ISO 13485 standard. Its primary focus is on the practical integration of the QMS into the strategic fabric of a medical device organization. While other courses may focus on theory, we emphasize the critical link between the standard and major global regulatory frameworks, such as the EU MDR and FDA QSR, providing participants with a holistic understanding of global compliance. Our methodology is deeply rooted in real-world application, utilizing case studies drawn from actual industry scenarios, including warning letters and product recalls, to illustrate the consequences of non-compliance and the benefits of a robust system. The curriculum is designed to empower participants to not only pass an audit but to build and sustain a culture of quality that drives efficiency, reduces risk, and supports product innovation. The expertise of the instructors at BIG BEN Training Center ensures that the content is current, relevant, and delivered in a way that fosters critical thinking, enabling attendees to return to their organizations ready to implement meaningful and sustainable improvements to their quality management systems.