BSI Training Academy
ISO 13485:2016 Requirements

Level 1

The ISO 13485 standard is an effective solution to meet the comprehensive requirements for a QMS. Adopting ISO 13485 provides a practical foundation for manufacturers to address the Medical Device Directives, regulations and responsibilities as well as demonstrating a commitment to the safety and quality of medical devices.

- Length: **1 day**
- Led by a **BSI expert tutor**
- **Teaching materials** are for personal use

Gain a better insight into the use of ISO 13485:2016 as the basis for a Quality Management System (QMS) implemented by medical device manufacturers. This course explores the requirements of ISO 13485:2016, discussing key principles and how the standard interacts with ISO 9001:2015, the European Medical Device Directives and US FDA's Quality System Regulation. The relationship with ISO 14971 "Application of Risk Management to Medical Devices" is also explored during the course.

This is the course for you if:

- You are new to ISO 13485:2016 standard
- You need to understand ISO 13485:2016 requirements
- You're planning, implementing, or maintaining ISO 13485:2016
- You're part of a team involved with ISO 13485:2016
- You need to gain an awareness of the relationship between ISO 13485 and ISO 14971

How will I benefit?

- Compare the requirements between ISO 13485 and ISO 9001
- Interpret the clauses of ISO 13485 using ISO 14969
- Recognize the role and responsibilities of management in ISO 13485
- Recognize the relationship between ISO 13485 and ISO 14971
- Compare the requirements between ISO 13485 and FDA's Quality System Regulation
- Appreciate the use of ISO 13485 as the basis of Medical Device Regulations worldwide.

Certificate

Upon successful completion of your course, you'll receive an **internationally recognized BSI certificate.**

bsi.

...making excellence a habit.™

Your training journey

We understand the challenges of meeting regulatory requirements and maintaining quality management systems. We understand because it's what we do, every day of every week; for you, for your customers, and for your bottom line.

We have dynamic course owners around the world, allowing delivery of training in many local languages. Our course owners are subject matter experts and use practical examples from their experiences to bring each lesson to life.

By working closely with you and fully understanding your requirements, we can create a training solution that meets the needs of your organization, whether you're training on existing standards, regulatory approval, or business improvement. We're one of few certification bodies offering diverse medical device training portfolios consisting of specialized training classes.

In-company

You can have this course delivered to your team on-site so it can be adapted to your learning needs.

Hebrew

All our training courses are delivered in Hebrew.
Training material is in English.

Related courses

Want to learn more?
Discover all training courses on our website.
www.bsigroup.com/en-IL

During the course, you will receive a copy of ISO 13485:2016 **only for consultation**.

Book your place on www.bsigroup.com/en-IL

Agenda

Day 1

- Welcome, benefits to you, and introductions
- Course aims, objectives and structure
- Quality definitions and the process approach
- Definition of a medical device within the industry
- Introduction to ISO 13485
- ISO 13485 in detail
- Clauses 0, 1, 2 and 3
- Clause 4 and 5
- Clause 6: Resource management
- Clause 7: Product realization including risk management
- Clause 8: Monitoring and measurement
- ISO 13485, FDA, QSR, MDSAP and other regulations
- Reflection and feedback

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