



BSI Training Academy

Implementing ISO 13485:2016

Level



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.

Develop your knowledge and skills in the process of implementing ISO 13485:2016 within your organization. Thanks to this course you'll be introduced to the concepts needed to understand, develop and implement a Quality Management System (QMS). This course provides the knowledge and process steps to enable the effective implementation of a QMS that is in line with the requirements for ISO 13485:2016 certification.

- Length: **2 days**
- Led by a **BSI expert tutor**
- **Teaching material** are for personal use

This is the course for you if:

- You already have a thorough knowledge of ISO 13485:2016 Quality Management
- You need to manage and implement a ISO 13485 QMS
- You are a manager who is responsible for managing and implementing a ISO 13485 QMS
- You need to conduct a base line review of an organization's current position with regard to ISO 13485:2016

How will I benefit?

- Understand how to implement a QMS as required by medical device directives
- Plan the implementation of ISO 13485:2016 within your organization
- Take the first steps towards ISO 13485:2016 certification
- Identify how you can better meet regulatory requirements
- Find ways to increase efficiency and add value through quality management
- Monitor supply chains to achieve continuous improvement

Certificate



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

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
- Boundaries: Conflict of interest and expertise
- Course aim, learning objectives and course structure
- Fundamentals of management systems
- Fundamentals of an ISO 13485 QMS
- Overview of ISO 13485
- The purpose, structure and requirements of ISO 13485
- Implementation:
 - Implementation process
 - Implementation outline
 - Gain top management commitment
 - Promote awareness
 - Perform gap analysis
 - Review current system
 - Identify risks and opportunities

Day 2

- Welcome back and review of day 1
- Develop implementation plan
- Approve the implementation plan
- Operate and assess the system
- Continual improvement
- Certification and registration
- Course review and final questions

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