



BSI Training Academy

ISO 13485:2016 Senior Management Briefing

Level

1C

The ISO 13485 standard is an effective solution to meet the comprehensive requirements for a Quality Management System. 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.

As a leader, your commitment and support is crucial to the success of your organization's ISO 13485:2016 Medical Devices Quality Management System (QMS). This interactive briefing has been designed around the requirements of the standard and highlights your responsibilities in terms of leadership and commitment. The focus is on helping senior management migrate their system from ISO 13485:2003 to ISO 13485:2016. You will gain a better understanding of your organization's obligations and develop action plans for managing the transition.

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

This is the course for you if:

- You are a senior manager of an organization implementing or running an ISO 13485:2016 QMS
- You already have a thorough knowledge of 13485:2016 Quality Management
- You need to identify ISO 13485:2016 management leadership and commitment requirements and highlight the changes from ISO 13485:2003 to ISO 13485:2016.

How will I benefit?

- Demonstrate your organization's commitment to medical devices quality
- Ensure quality objectives are established at all levels and functions
- Allocate resources for the implementation or development of your ISO 13485:2016 QMS
- Participate in improvement projects and show support by leading by example
- Communicate the importance of meeting customer and regulatory requirements

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 and introductions
- Briefing aim and structure
- ISO 13485:2016, ISO 9001:2015 and HLS
- ISO 13485 QMS and top management
- Overview of key changes
- Transition process and timings
- Developing a plan
- BSI resources
- Review and final questions

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