BSI Training Academy

ISO 13485:2016 Lead Auditor

Level 1 2 3

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.

Gain the confidence to effectively audit a QMS in accordance with internationally recognized best practice techniques. Demonstrate your commitment to the quality of medical devices by transforming existing auditor skills to ISO 13485:2016. Consolidate your expertise with the latest developments and contribute to the continuous improvement of the business.

- Length: **5 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 13485:2016 Quality Management
- You need to lead a second party audit in your organization
- You are a manager who is responsible for a team of internal auditors
- You want to gain internationally recognized best practice auditing techniques so you can lead auditing activities in your organization

How will I benefit?

- Identify the aims and benefits of an ISO 13485:2016 audit
- Interpret ISO 13485:2016 requirements for audit application
- Plan, conduct and follow-up auditing activities that add real value
- Grasp the application of risk-based thinking, leadership and process management
- Access the latest lead auditor techniques and identify appropriate use
- Build stakeholder confidence by managing processes in line with the latest requirements
- Understand the arrangements for BSI certification.

Certificate

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

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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**

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Agenda

Day 1

- First, second and third party audits
- Typical audit activities
- Audit objectives, scopes and criteria
- Audit resources
- Roles, responsibilities and confidentiality
- Audit methods
- Stage 1 audit
- Stage 2 audit
- Audit plan
- Work documents
- Opening meeting
- Audit evidence
- Effective communication
- Audit findings
- Audit meetings
- Closing meeting
- Audit reports
- Audit follow-up

Day 2

- Purpose and business benefits of a QMS
- Terminology
- Plan-Do-Check-Act
- QMS processes and context
- Role of the auditor
- QMS documentation
- SKILLS
- Initiating the audit
- Document review
- Audit plan
- Work documents
- Opening meeting
- Observations
- Auditing top management

Day 3

- Specimen exam: Sections 1 and 2 review
- Auditing planning to meet requirements
- Tutorial on body language
- Auditing design and development
- Audit trails
- Auditing production and service provision
- Auditing monitoring and measurement

Day 4

- Specimen exam: Section 3 review
- Auditing improvement
- Nonconformities
- Closing meeting
- Audit report
- Audit follow-up
- Specimen exam: Section 4

Day 5

- Receive homework – audit report from student
- Final questions/final revision
- Evaluation
- Introduction/readiness to the exam
- Exam

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