BSI Training Academy

ISO 13485:2016
Lead Auditor

Five day course

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.

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 auditor techniques and identify appropriate use
- Build stakeholder confidence by managing processes in line with the latest requirements
- Understand the arrangements for BSI certification.

What will I learn?

- Gain the skills to plan, conduct, report and follow up an audit in accordance with ISO 19011
- Identify the purpose and benefits of an ISO 13485:2016 QMS
- Explain the role of an auditor to plan, conduct, report and follow up an audit in accordance with ISO 19011 (and ISO 17021 where appropriate).

Who should attend?

Anyone with the need to audit an organization's ISO 13485:2016 QMS.

Book this course online by visiting bsigroup.ca/training or call us today on +1 800 862 6752

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...making excellence a habit.™

BSI Training Academy

Agenda

Day 1

- Welcome & introductions
- Course benefits
- Aims, objectives & structure
- First, second & third party audits
- Typical audit activities
- Audit objectives, scopes & criteria's
- Audit resources
- Roles, responsibilities & 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 & business benefits of a QMS
- Terminology
- Plan-Do-Check-Act
- Processes & context
- Role of the auditor
- QMS documentation
- Initiating the audit
- Document review
- Audit plan
- Work documents
- Opening meeting
- Observations
- Auditing top management

Day 3

- Specimen exam: Sections 1 & 2 review
- Auditing: Planning to meet requirements
- Auditing: Design & development
- Tutorial on body language
- Audit Trails
- Auditing: Purchasing
- Auditing: Monitoring & measurement

Day 4

- Specimen Exam: Section 3 review
- Auditing: Improvement
- Nonconformities
- Closing Meeting
- Audit report
- Audit follow-up
- Specimen exam: Section 4

Day 5

- Hand in homework: Audit report
- Final questions/revision
- BSI Registered Auditor Qualification
- Evaluation
- Introduction to the exam
- Exam
- Reflection & feedback

Why train with us?

We don't just train you to meet standards - we create them. As the world's first National Standards Body and a founding member of ISO, no one knows standards like BSI. Our expert knowledge means a lot and when you train with us, you benefit from this expertise. Our training courses will give you the knowledge and skills to embed the standards that matter to you the most. To promote your professional development, you'll also receive a BSI Training Academy certificate that's recognized worldwide.

Book today by visiting bsigroup.ca/training

Toronto Office
6205B Airport Road, Suite 414
Mississauga, ON L4V 1E3
T: 416 620 9991
TF: 1 800 862 6752
F: 416 620 9911

Ottawa Office
515 Legget Drive, Suite 110
Ottawa, ON K2K 3G4
T: 613 271 7007
TF: 1 800 862 6752
F: 613 271 9007

Montréal
1, Place Ville Marie, Suite 2901
Montréal, QC H3B 2C4
T: 514 940 1778
TF: 1 800 862 6752
F: 514 866 2115

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