Medical Devices | Lead Auditor ISO 13485

International Training

Number of days 5

Key information about the course

From managing an audit program to reporting on results, this lead auditor training course teaches you everything needed to conduct a quality management system (QMS) audit.

Led by experienced instructors over five days, the training is suited to quality managers, directors, engineers, or consultants. It will help you fully identify the benefits of a QMS and explain the role of the auditor.

On completing this stage of your learning journey, you will be able to apply risk-based thinking, leadership and process management and understand the arrangements for BSI certification.

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Agenda

Day 1

- Benefits to you, welcome and introductions
- Course aims, objectives and structure
- **Knowledge**
- First, second- and third-party audits
- Typical audit activities
- Audit objectives, scopes and criteria's
- Audit resources
- Roles and 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
- Close day 1

Day 2

- Day 1 review
- **Knowledge continued**
- 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
- Close day 2

Once you have completed the training, you will receive a BSI training certificate.

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Day 3

- Specimen exam: Sections 1 and 2 review
- **Skills**
- Auditing planning to meet requirements
- Auditing design and development
- Tutorial on body language
- Audit trails
- Auditing production and service provision
- Auditing monitoring and measurement
- Close Day 3

Day 4

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

Day 5

- Hand in homework – audit report
- Final questions/final revision
- Evaluation
- Introduction/readiness to the exam
- Exam
- End of course

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Pedagogical objectives

- Identify the aims and benefits of an ISO 13485:2016 audit
- Plan, conduct and follow up on auditing activities
- Build stakeholder confidence by understanding the latest requirements

Skills to be acquired

On completion of this training, participants will be able to:

- 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 in planning, conducting, reporting and following up an audit in accordance with ISO 19011 (and ISO 17021 where appropriate)

Targeted audience

- Medical device quality professionals interested in conducting first-party, second-party, and/or third-party audits
- Management representatives
- Quality directors, managers, and engineers
- Consultants

Pedagogical, technical and framing means

Course materials including:

- Introduction to the training, detailed program and security assignments
- Course presentation, theory and activities/ role plays
- Answers to the activities
- Videos
- Additional documents, distributed during the sessions, to use for the activities
- Attendance sheet to be signed

Assessment specifics

- Questionnaire to assess the knowledge at the end of the training
- Customer survey

What is included ?

- Course materials, provided electronically
- Letter of attestation
- Official certificate

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Prerequisites: A good knowledge of the ISO 13485 is recommended prior to starting this course.

These training modules are eligible to the subsidizing by the public institutions in France (OPCO);

Each delegate receives a training convention after the enrollment.

Please note that for the public sessions, you have until 48h before the start of the course to confirm your enrollment. For the in-house sessions, the deadline would be of two weeks prior to the start of the course.

Should you be in a disabled situation, please contact us and indicate what details should be taken into account.

You can contact us on **training.france@bsigroup.com** or **01 89 79 00 40**

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