Medical Devices | Internal Auditor ISO 13485:2016

International Training

Number of days 2

Key information about the course

Designed by your partner in learning as an intensive course for medical device quality professionals, this ISO 13485 internal auditor training builds knowledge for an effective quality management system.

The two-day training is delivered either in person or live online in a classroom environment. Guided by experienced instructors, you will learn how to explain the structure and scope of the standard and identify an auditor's key responsibilities. You'll also discuss every stage of the internal audit process through role-play, workshops and tutorials, plan and conduct an audit and assess if it was done effectively.

Although some prior understanding of ISO 13485:2016 is useful, you'll leave the course with all the knowledge you need. You'll be able to maintain compliance and internal processes and motivate colleagues to do the same.

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Agenda

Day 1

- Welcome, benefits, delegate introductions and course aim
- Boundaries: Conflict of interest and expertise
- Learning objectives and course structure
- Fundamentals of quality management: ISO 13485 and the relationship to ISO 9000 series of standards and ISO 14971 (risk management)
- Use of ISO 13485 in relation to compliance with worldwide regulatory re-quirements
- Introduction to auditing: What is an audit?
- The process approach and process auditing
- Managing an audit program
- Audit activities
- Auditor competence and responsibilities
- Plan an internal audit
- Create work documents
- Conducting an (informal) opening meeting
- Collecting and verifying audit information
- Audit techniques
- Gathering and verifying information
- Introduction of audit findings and nonconformities
- Conducting an audit
- Wrap up day 1

Day 2

- Review of day 1
- Conducting the audit (Part 2)
- Generate audit findings
- Identify and define nonconformities
- Prepare audit conclusions
- Write an audit report
- Closing meeting
- Conduct audit follow-up
- Course summary
- End of course

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

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Pedagogical objectives

- Able to fully grasp and comply with ISO 13485:2016
- Confidence that your organization is using competent auditors
- Maintain rigorous internal processes
- Write factual audit reports and suggest corrective actions

Skills to be acquired

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

- Explain the structure and scope of ISO 13485:2016 and how it applies to the organization seeking regulatory compliance
- Identify the key principles of auditing and auditor responsibilities
- Plan an internal audit
- Conduct an effective audit based on process identification, sampling and questioning
- Determine if corrective action has been effectively implemented

Targeted audience

- Medical device quality professionals with knowledge of quality management systems and ISO 13485:2016
- Individuals interested in conducting first-party or second-party audits
- Management representatives
- Internal auditors
- 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: There are no formal prerequisites for 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 enrolment.

Please note that for the public sessions, you have until 48h before the start of the course to confirm your enrolment. 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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