



ISO 13485 Internal Auditor - International



Your partner
in progress



Course descriptive

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.

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

Upon completion of this training, delegates 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

Prerequisites

There are no formal prerequisites for this course.

Duration

2 days – 14 hours



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



Agenda - Day 1

Time	Topic
09:00	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 requirements
	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
	17:00



Day 2

Time	Topic
09:00	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
17:00	End of course

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

**Each delegate receives a training convention after 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 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**.