



ISO 13485 Lead Auditor - International



Your partner
in progress



Course descriptive

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.

You'll grasp the key principles and practices of effective QMS audits in line with ISO 13485:2016 and ISO 19011 "Guidelines for auditing management systems". Using a step-by-step approach, you'll be guided through the entire audit process from initiation to follow-up. Over 5 days, you'll gain the knowledge and skills required to undertake and lead a successful management systems audit. Learn to describe the purpose of an ISO 13485:2016 QMS audit and satisfy third-party certification. Acquire the skills to plan, conduct, report and follow up a QMS audit that establishes conformity and enhances overall organizational performance.

Pedagogical objectives

Upon completion of this training, delegates will be able to:

- 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

Skills to be acquired

Upon completion of this training, delegates 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 to plan, conduct, report and follow 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

You should have a good knowledge of ISO 13485:2016 and the key principles of a QMS. If not, we strongly recommend you attend our ISO 13485:2016 Introduction course or ISO 13485:2016 Clause by Clause course first as there are particular requirements you need to understand before you can be an auditor. Note! The requirements of ISO 13485 are not taught in this training.

Prerequisites

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

Duration

5 days – 35 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
08:30	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
17:30	Close day 1



Day 2

Time	Topic
08:30	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
18:00	Close day 2



Day 3

Time	Topic	
08:30	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	
	18:00	Close day 3

Day 4

Time	Topic
08:30	Specimen exam: Section 3 review
	SKILLS
	Auditing improvement
	Nonconformities
	Closing meeting
	Audit report
	Audit follow-up
	Specimen exam: Section 4
18:00	Close day 4



Day 5

Time	Topic
08:00	Hand in homework – audit report
	Final questions/final revision
	Evaluation
10:15	Introduction/readiness to the exam
	Exam
12:15	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**.