ISO 13485 Lead Auditor CQI/IRCA - International

Your partner in progress

Course descriptive

Gain the confidence to effectively audit a QMS in accordance with internationally recognized best practice techniques against the requirements of ISO13485:2016. Consolidate your expertise with the latest developments and contribute to the continuous improvement of your quality system, leading to greater patient safety. 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. You'll acquire the skills to plan, conduct, report and follow up a QMS audit that establishes conformity and enhances overall organizational performance.

Pedagogical objectives

Successful completion of this CQI and IRCA certified training course by passing the relevant CQI and IRCA examination and skills assessment, will demonstrate knowledge and basic skills to undertake and lead a management system audit.

Skills to be acquired

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

- Describe the purpose of a quality management system, of quality management systems standards, of management system audit and of third-party certification
- Explain the role of an auditor to plan, conduct, report and follow up a quality management system audit in accordance with ISO 19011 (and ISO 17021 where appropriate)
- Plan, conduct, report and follow up an audit of a quality management system to establish conformity (or otherwise) with ISO 13485 and in accordance with ISO 19011 (and ISO 17021 where appropriate)

Targeted audience

- Medical Device professionals interested in conducting first-party, second-party, and/or third-party audits
- Management Representatives
- Quality Directors
- Consultants

Prerequisites

Before attending this course, delegates are expected to have:

- Knowledge of the following quality management principles and concepts:
    - The Plan, Do, Check, Act (PDCA) cycle
    - The relationship between quality management and customer satisfaction
    - Commonly used quality management terms and definitions and the 8 Quality Principles as given in ISO 9000
    - The process approach used in quality management
    - The Model of a Process Based Quality Management System, the structure and content of ISO 13485
- Knowledge of the requirements of ISO 13485

It is advisable that delegates have either attended an internal auditor course or had experience with conducting internal or supplier audits.

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
	Introduction/readiness to the exam
10:15	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**.