Medical Devices | CQI and IRCA Certified Medical Devices | Quality Management Systems Auditor/Lead Auditor | ISO 13485:2016

International Training

Number of days **5**

Key information about the course

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.

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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
- Tutorial on body language
- **Auditing design and development**
- 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

- **Receive homework - audit report from delegate**
- **The certification and accreditation process, the role of CQI and IRCA, the CQI and IRCA QMS auditor certification requirements and code of conduct**
- **Final questions/final revision**
- **Evaluation**
- Introduction/readiness to the exam
- Exam
- End of course

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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

On completion of this training, participants 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 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

bsi.

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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.

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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