Medical Devices – Quality Management Systems Auditor/Lead Auditor Course (ISO 13485)

Course Description

BSI's "Lead Auditor: ISO 13485" course teaches the principles and practices of effective quality management systems and process audits in accordance with ISO 13485 and ISO 19011, "Guidelines for Quality and/or Environmental Management Systems Auditing."

Experienced instructors guide students through the entire audit process, from managing an audit programme to reporting on audit results. Participants will gain necessary auditing skills through a balance of formal classroom tutorials, practical role-playing, group workshops, and open forum discussions.

Learning Objectives

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

- Interpret the requirements of ISO 13485 in the context of an audit
- Explain the relationship with ISO/TR 14969 and the ISO 9000 series
- Describe the purpose of a quality management system and explain the 8 principles of quality management
- Explain the role of an auditor to plan, conduct, report and follow up a quality management system audit in accordance with ISO 19011
- Plan, conduct, report and follow-up on a QMS audit in accordance with ISO 19011 and by interpreting ISO 13485
- Manage the duties of a lead auditor in their organization or for a third-party.

Intended Audience

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

Course Duration

Five Days

There is a written exam on Day 5.

Prerequisites

This course teaches auditing principles using ISO 13485, therefore a basic knowledge of ISO 13485 and its application within a Medical Device organization is strongly recommended together with internal audit experience.

Further Information

IRCA Certified Course (A17579)
This course is certified by the International Register of Certificated Auditors (IRCA) and meets the training requirements for IRCA QMS 2008 auditor certification.

How will I learn?

We use accelerated learning techniques that encourage interaction and collaboration, keep the course varied and put your learning in context. Our tutors are the best in their field and will make sure your learning needs are met. Choose between public or in-company courses tailored to your business – whatever delivers the most positive and successful outcome for you.

Where will I learn?

We deliver five star learning at first class venues. Each venue has been selected to provide the best possible learning environment so you can maximize your learning experience.

Who are we?

As an EU Notified Body, our expertise is in auditing to the requirements of the Directives. Our tutors are skilled in transferring knowledge contained within each standard to help you embed excellence within your organization. With over 65,000 clients in 150 countries worldwide, you can trust BSI to help you perform better, reduce risk and grow sustainably.

Why train with us?

We've trained and audited thousands of businesses using the same standards so we can genuinely benchmark performance. And we can take you from beginner to certification quickly then support you with follow-up courses and webinars – and all this for the price of your course.

Did you know?

Our tutors are active practitioners in their subjects, ensuring the latest developments are fully understood. We are the leaders in medical devices regulatory expertise with over 200 BSI Medical Device product and regulation experts around the world.

Next step:

To book this course, call one of our dedicated training experts on +44 845 086 9000 or book online at bsigroup.co.uk/training

In-company Training

Discuss your product development in confidential surroundings by opting for bespoke in-company training.