

Internal Auditor: ISO 13485

Course Description

BSI's "Internal Auditor: ISO 13485" course is intended for medical device quality professionals aiming to build on their current knowledge of ISO 13485 and evaluate the effectiveness of the quality management system in their organization.

This intensive two-day course teaches the principles and practices of effective quality management systems process audits in accordance with the ISO 13485 and ISO 19011. An experienced instructor guides students through the internal audit process, from planning an audit to reporting on audit results and following up on corrective actions. Participants will gain necessary auditing skills through a balance of formal classroom tutorials, practical role-playing, and group workshops.

Learning Objectives

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

- Explain the structure and scope of ISO 13485 management system standard and how it applies to the organization aiming for regulatory compliance worldwide.
- Identify the principles of auditing and auditor responsibilities.
- Plan an internal audit.
- Conduct informal opening and closing meetings.
- Conduct an audit based on process identification, sampling and questioning.
- Provide verbal and written feedback.
- Document concise nonconformities.
- Effectively report on an audit.
- Follow-up on corrective actions.

Intended Audience

- Medical Device Quality professionals with knowledge of quality management systems and ISO 13485
- Individuals interested in conducting first-party or second-party audits
- Management representatives
- Internal auditors
- Managers
- Consultants.

Course Duration

Two days.

Prerequisites

This course does not detail the requirements of ISO 13485.

Prior knowledge of the ISO 13485 standard, such as the overview provided in BSI's 'Introduction to ISO 13485 or previous work with ISO 13485 in an organization, is strongly recommended as a prerequisite for this course.

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](https://www.bsigroup.co.uk/training)

In-company Training

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