

Implementing ISO 13485

Course Description

BSI's "Implementing: ISO 13485" two-day course has been designed to provide participants with the knowledge and process steps to enable them to effectively implement a quality management system in line with the requirements for ISO 13485:2003 certification.

The course introduces the concepts needed to understand, develop, and implement a quality management system.

Learning Objectives

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

- Describe the fundamentals of quality management systems
- Explain the purpose, structure and requirements of ISO 13485
- Apply a process of implementing a quality management system that meets the requirements of ISO 13485
- Prepare for ISO 13485 certification.

Intended Audience

- Anyone involved in defining, planning, or implementing an ISO 13485 based quality management system
- Management representatives
- Implementation team members.

Course Duration

Two days.

Prerequisites

Designed for individuals with little or no previous knowledge of implementing a quality management system. Basic knowledge of medical devices, ISO 9001, or ISO 13485 would be beneficial.

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.