

Implementing ISO 13485 Medical Device Quality

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.

Course Benefits

- Take the first steps towards ISO 13485 certification
- Understand how you can better meet customer and regulatory requirements
- Find ways to increase efficiency and cost savings through quality management
- Monitor supply chains to achieve continuous improvement

Learning Objectives

Upon completion of this training, delegates 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

2 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.