

ISO 13485 Medical Device Management Systems Implementation Course

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:

Upon 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

Who Should Attend:

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

Course Duration:

Two days.

Prerequisite for the Course:

This course is designed for individuals with little or no previous knowledge of implementing a quality management system. A basic knowledge of medical devices, ISO 9001:2008, or ISO 13485:2003 would be beneficial.

