



# BSI Training Academy

## ISO 13485 Introduction & Implementation

### training course

#### Essential information about the course

Level 

BSI's "Introduction & Implementing: ISO 13485" two-day course has been designed to provide participants an insight in to the use of ISO 13485 as the basis for a quality management system implemented by medical device manufacturers and enable them to effectively implement a quality management system in line with the requirements for ISO 13485 certification. The course introduces the concepts needed to understand, develop, and implement a quality management system.

#### Make sure this is the right course for you.

##### This is the course for you if:

- Anyone involved in defining, planning, or implementing an ISO 13485 based quality management system
- Management representatives
- Implementation team members.
- Senior Management
- Quality Managers
- Regulatory Affairs Managers
- Internal and external Auditors

##### What is the course like?

- Two day long
- Led by a BSI expert tutor
- Relaxed and comfortable learning environment
- You will receive detailed course notes

##### How will I benefit?

- Compare the requirements, clauses and relationship between ISO 13485 and ISO 9001, ISO 14969, ISO 14971 and FDA's Quality System Regulation
- 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.



Upon successful completion of your course, you'll receive an internationally recognized BSI certificate.

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### Contact us

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