

ISO 13485:2016 Implementation

Two day course

Develop your knowledge and skills in the process of implementing ISO 13485:2016 within your organization. You'll be introduced to the concepts needed to understand, develop and implement a Quality Management System (QMS). This course provides the knowledge and process steps to enable the effective implementation of a QMS that is in line with the requirements for ISO 13485:2016 certification.



How will I benefit?

- Understand how to implement a QMS as required by medical device directives
- Plan the implementation of ISO 13485:2016 within your organization
- Take the first steps towards ISO 13485:2016 certification
- Identify how you can better meet regulatory requirements
- Find ways to increase efficiency and add value through quality management
- Monitor supply chains to achieve continuous improvement.



What will I learn?

- Define a ISO 13485:2016 QMS
- Identify the steps for defining, planning, organizing and scheduling necessary activities
- Implement an effective quality management system
- Conduct a base line review of an organization's current position with regard to ISO 13485:2016.



Who should attend?

Anyone involved in defining, planning, or implementing an ISO 13485:2016 QMS, as well as management representatives and implementation team members.

Book this course online by visiting bsigroup.com/training or call us today on +44 345 086 9000

BSI Training Academy

Agenda

Day 1

- Welcome & introductions
- Course benefits
- Aims, objectives & structure
- Boundaries: Conflict of interest & expertise
- Management systems fundamentals
- ISO 13485:2016 QMS
- ISO 13485:2016 purpose, structure & requirements
- Implementation process
- Implementation outline
- Top management commitment
- Promoting awareness
- Performing gap analysis
- Reviewing current system
- Identifying risks & opportunities

Day 2

- Review of Day 1
- Develop implementation plan
- Approve implementation plan
- Operate & assess the system
- Continual improvement
- Certification & registration
- Course review & questions
- Reflection & feedback

Our knowledge

We don't just train you to meet standards – we create them. As the world's first National Standards Body and a founding member of ISO, no one knows standards like BSI. Our expert knowledge means a lot and when you train with us, you benefit from this expertise.

Our tutors

Our tutors are the best in the business. As experienced assessors, they'll transfer the knowledge you need to embed standards into your organization and develop them through continual improvement.

Our approach

Our high impact accelerated learning approach is proven to fast-track learning by improving knowledge retention and skill application. This course is activity based, resulting in a deeper understanding of material and greater impact on job performance.

Your expertise

Our training courses will give you the knowledge and skills to embed the standards that matter to you the most. To promote your professional development, you'll receive a personalized BSI Training Academy certificate that's recognized worldwide.

Book today by visiting bsigroup.com/training

Kitemark Court, Davy Avenue,
Knowlhill, Milton Keynes, MK5 8PP
T: +44 345 086 9000
E: training@bsigroup.com