

## ISO 13485:2016

### Introduction

#### One day course

Gain a better insight into the use of ISO 13485:2016 as the basis for a Quality Management System (QMS) implemented by medical device manufacturers. This course explores the requirements of ISO 13485:2016, discussing key principles and how the standard interacts with ISO 9001:2015, the European Medical Device Directives and US FDA's Quality System Regulation. The relationship with ISO 14971 'Application of Risk Management to Medical Devices' is also explored during the course.



#### How will I benefit?

- Take the first steps towards ISO 13485:2016 certification
- Understand how you can better meet regulatory requirements leading to increased patient safety
- Find ways to increase efficiency and cost savings through quality management
- Monitor supply chains to achieve continuous improvement
- Develop safe and effective medical devices
- Motivate employees through CPD.



#### What will I learn?

- Use of ISO 13485:2016 as the basis for a QMS for medical device manufacturers
- Relationship between ISO 13485:2016 and European Medical Device Directives
- Use of ISO 13485:2016 as the basis of regulatory requirements worldwide.



#### Who should attend?

Senior management, quality managers, regulatory affairs managers, internal and external auditors, consultants and anyone involved with the implementation of the standard.

Book this course online by visiting [bsigroup.ca/training](https://bsigroup.ca/training) or call us today on +1 800 862 6752

# BSI Training Academy

## 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.

## Agenda

- Welcome & introductions
- Course benefits
- Aims, objectives & structure
- Quality definitions & process approach
- Medical devices within the industry
- Introduction to ISO 13485:2016
- ISO 13485:2016 in detail
- Clauses 1, 2, & 3
- Clause 4 & 5
- Clause 6: Resource management
- Clause 7: Product realization
- Risk management
- Clause 8: Monitoring & measurement
- ISO 13485:2016 FDA, QSR, MDSAP & other regulations
- Reflection & feedback

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