

## ISO 13485:2016

# Clause by Clause

### Two day course

Demonstrate your ability to provide medical devices and related services that meet quality and regulatory demands in line with ISO 13485:2016 Medical Device requirements for a Quality Management System (QMS). This course enables a clause by clause understanding of ISO 13485:2016, providing an effective solution to meet the comprehensive requirements of an effective QMS.



#### How will I benefit?

- Be able to describe the requirements and structure of ISO 13485:2016
- Interpret and apply requirements relevant to your organization
- Appreciate how a QMS can be applied as a framework to produce safer medical devices
- Evaluate how requirements can be effectively implemented to meet and maintain regulatory compliance.



#### What will I learn?

- ISO 13485:2016 Requirements
- ISO 13485:2016 Scope and structure
- How requirements are established and maintained within an organization
- What systems are required for implementation
- How to gain or maintain certification to ISO 13485:2016.



#### 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

## Agenda

### Day 1

- Welcome & introductions
- Course benefits
- Aims, objectives & structure
- Conflict of interest & expertise
- Overview of ISO 13485:2016
- Activity 1: PDCA & ISO 13485:2016
- Discussion of Clause 1, 2 & 3
- Activity 2: Clauses 1, 2 & 3
- Overview of Clause 4
- Activity 3: Clause 4 Quality management system
- Clause 5
- Activity 4: Management responsibility
- Activity 5: Clause 6 resources

### Day 2

- Day 1 Review
- Product realization: Clause 7
- Measurement, analysis & improvement: Clause 8
- Linking it all together
- 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.ca/training](https://bsigroup.ca/training)

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