

## ISO 13485:2016

### Transition

#### Half day course

With greater attention on the organization's ability to meet applicable customer and regulatory requirements, ISO 13485:2016 focuses on the entire supply chain of the medical device industry, with added emphasis on risk management. This course will help you identify the gaps in your current Quality Management System (QMS) and start planning your transition and certification to comply with ISO 13485:2016.



#### How will I benefit?

- Recognize the key changes between ISO 13485:2003 and EN 13485:2012
- Understand how these changes may impact your current QMS
- Explore the relationship between ISO 9001:2015 High level structure and ISO13485:2016
- Consider transition timelines and what resources may be required.



#### What will I learn?

- Key changes between ISO 13485:2003, EN 13485:2012 and ISO 13485:2016
- Revised terms and definitions
- Relationship between ISO 9001:2015 high level structure and ISO 13485:2016
- Transition timelines and what resources may be required.



#### Who should attend?

Anyone involved in planning, implementing, auditing or supervising an ISO 13485:2016 QMS transition.

Book this course online by visiting [bsigroup.ca/training](http://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
- Current status of ISO 13485:2016
- Introduction to ISO 9001:2015
- High level structure
- How does ISO 13485:2016 fit into the global picture?
- Scope, terms & definitions
- Quality management system (Clause 4)
- Management responsibility (Clause 5)
- Resource management (Clause 6)
- Product realization & focus on the changes in design & development
- Overview of Clause 7 & 8 changes
- Planning your transition & timelines
- Summary of key changes
- Reflection & feedback

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