BSI Training Academy

ISO 13485:2016

Transition & Auditor Refresher

One day course

With greater attention on the organization's ability to meet applicable customer and regulatory requirements, the new ISO 13485:2016 focuses on the entire supply chain of the medical device industry, with added emphasis on risk management. Discover the latest requirements and explore the changes since ISO 13485:2003 and EN 13485:2012. You'll refresh your auditing techniques and be able to identify the gaps in your current

How will I benefit?

- Recognize the key changes between ISO 13485:2003/EN 13485:2012 and ISO 13485:2016
- Update your knowledge of audit principles, practices and terminology
- Refresh your skills to prepare for an ISO 13485:2016 audit
- Explore the relationship between ISO 9001:2015 High level structure and ISO 13485:2016
- Make a smooth transition to ISO 13485:2016 and understand what resources may be required
- Participate in audit workshop scenarios to apply the skills you've learnt.

What will I learn?

- Key changes and auditing techniques
- How these changes may impact your current QMS
- Revised terms, definitions and audit principles
- Developing an internal audit schedule and plan
- Relationship between ISO 13485:2016 and high level structure
- 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 or call us today on 1 800 862 6752

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...making excellence a habit.™

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 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.

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.

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
- 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
- Conflicts of interest and expertise
- ISO 13485:2016 Clause 8.2.4
- Internal audit
- Audit planning
- Areas of increased emphasis
- Why do we audit and how do we perform a good audit?
- Conducting the audit: audit records
- Audit workshop
- Transition
- Reflection & feedback

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