



BSI Training Academy

ISO 13485:2016 Senior Management Briefing

Essential information about the course

Level **1C**

As the internationally recognized best practice for a Quality Management System (QMS) implemented by medical device manufacturers, ISO 13485:2016 helps organizations to meet applicable customer and regulatory requirements. So it's no surprise that companies invest in training their people to get the knowledge and skills to use ISO 13485 to focus on their medical device supply chain and risk management.

As a leader, your commitment and support is crucial to the success of your organization's

management system for ISO 13485. This executive level briefing is designed to give you an introduction to the standard and the changes to ensure quality objectives are established and met. You will also learn about your organization's obligations and your leadership responsibilities within the management system.

This interactive session is led by our expert tutors who have years of experience in the medical industry. Upon completion you will be able to develop action plans for implementing key leadership activities.

Our full briefing agenda helps you understand what to expect

- Welcome and introductions
- Briefing aims and structure
- ISO 13485:2016 and the High Level Structure
 - Purpose and industry applicability
 - Annex SL
 - Plan-Do-Check-Act
 - ISO 13485 and ISO 9001 structure and clauses
- ISO 13485 QMS and top management
 - Process model
 - Clause 5: Leadership
 - Leadership requirements
- Overview of key changes in the standard
 - What's new
 - Areas of emphasis
 - Regulatory requirements
 - Key additions to Clauses 4, 5, 6, 7 and 8
 - Design and development
 - Product realization
- Transition process and timings
- Developing a plan
 - Where are you now and what do you need to do
 - Success factors
- Review and final questions

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We want to make sure you have the best learning experience possible. That's why we offer a range of training courses from beginner to expert. We create a positive learning environment so you retain the knowledge and acquire skills that will continue to be of use beyond the course.

Make sure this is the right course for you.

This course is for you if:

- You are a leader in your organization
- You are involved in the future planning, implementing, maintaining or auditing of an ISO 13485 QMS

What's the course like?

- Two hours
- Led by a BSI expert tutor
- Relaxed and comfortable learning environment
- You'll receive course materials to take away

How will I benefit?

- Understand the main standard requirements
- Ensure quality objectives are established at all levels
- Be able to show leadership and commitment in relation to your ISO 13485 QMS
- Allocate resources for the implementation/development of your ISO 13485 QMS
- Develop professionally
- Network with likeminded peers

Why invest in training from BSI?

Our tutors are the best in the business. They're truly passionate about sharing their knowledge and ensuring you learn. Trusted experts with years of hands-on and business experience, they bring the subject matter to life with relevant and contemporary examples to enhance your learning.

Training delivered in-house only



Contact us for a customized quote
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Talk to one of our experts to find out more



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