Medical Devices | ISO 13485:2016 Clause by Clause

International Training

Number of days 2

Key information about the course

This two-day course provides an in-depth understanding of ISO 13485:2016. It's designed specifically for those who are looking to further their knowledge of the management system.

Training will be delivered either live and online or in-person in a classroom setting. You will learn how to explain the scope and structure of ISO 13485:2016 and interpret what's required for your own organization.

You will finish this stage of your learning journey with deeper knowledge and confidence and have a clear pathway for putting ISO 13485:2016 certification into place for any organization.

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Agenda

Day 1

- Benefits to you, welcome and introductions
- Boundaries: Conflict of interest and expertise, course aims, learning objec-tives and course structure
- Overview of quality management systems
- Overview of ISO 13485
- ISO 13485 Clauses 0, 1, 2 and 3
- Quality management system: Clause 4
- Management responsibility: Clause 5
- Resource management: Clause 6
- Summary day 1

Day 2

- Welcome back and review of day 1
- Product realization: Clause 7
- Measurement, analysis and improvement: Clause 8
- Linking it all together
- Wrap up course

Once you have completed the training, you will receive a BSI training certificate.

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Pedagogical objectives

- Full understanding of ISO 13485:2016 requirements
- Able to explain and interpret requirements, relevant to your organization
- Learn how a quality management system provides a framework for safer medical devices
- Comprehensive training notes and 14 CPD points on completion

Skills to be acquired

- Explain the scope and the structure of ISO 13485:2016
- Describe the requirements of ISO 13485:2016
- Explain how to interpret the requirements of the standard within your organization
- Develop your knowledge of how the requirements of ISO 13485:2016 are established and maintained in an organization
- Identify the systems that are required to implement an ISO 13485:2016 QMS in order to gain or maintain certification to ISO 13485:2016

Targeted audience

- Regulatory, quality, research, design, development, and manufacturing personnel who will be involved in working with ISO 13485:2016 and need to have a greater understanding of the management system
- Organizations preparing to put ISO 13485:2016 in place
- Personnel who have joined an organization who have ISO 13485:2016 and require in depth knowledge
- Delegates attending the Lead Auditor to ISO 13485:2016 course who do not already have a good knowledge of the standard

Pedagogical, technical and framing means

Course materials including:

- Introduction to the training, detailed program and security assignments
- Course presentation, theory and activities/ role plays
- Answers to the activities
- Videos
- Additional documents, distributed during the sessions, to use for the activities
- Attendance sheet to be signed

Assessment specifics

- Questionnaire to assess the knowledge at the end of the training
- Customer survey

What is included ?

- Course materials, provided electronically
- Letter of attestation
- Official certificate

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Prerequisites: There are no formal prerequisites for this course

These training modules are eligible to the subsidizing by the public institutions in France (OPCO);

Each delegate receives a training convention after the enrolment.

Please note that for the public sessions, you have until 48h before the start of the course to confirm your enrolment. For the in-house sessions, the deadline would be of two weeks prior to the start of the course.

Should you be in a disabled situation, please contact us and indicate what details should be taken into account.

You can contact us on **training.france@bsigroup.com** or **01 89 79 00 40**

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