

ISO 13485 Clause by Clause - International

Your partner
in progress

Course descriptive

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.

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

Upon completion of this training, delegates will be able to:

- 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

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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

Prerequisites

There are no formal prerequisites for this course.

Duration

2 days – 14 hours

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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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Agenda - Day 1

Time	Topic
09:00	Benefits to you, welcome and introductions
	Boundaries: Conflict of interest and expertise, course aims, learning objectives 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
17:00	Close day 1

Day 2

Time	Topic
09:00	Welcome back and review of day 1
	Product realization: Clause 7
	Measurement, analysis and improvement: Clause 8
	Linking it all together
17:00	Wrap up course

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

**Each delegate receives a training convention after 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 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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