



# ISO 13485 Implementation - International



Your partner  
in progress



## Course descriptive

This two-day course gives you the knowledge and steps to implement a quality management system (QMS) in line with ISO 13485:2016. It's suitable for managers or members of an implementation team.

Choose to take this stage of your learning journey in-person or live online in a classroom environment. You'll learn how to plan, organize and schedule everything needed to define an ISO 13485: 2016 QMS, as well as how to implement it. You'll also carry out a baseline review, specific to your own organization.

On completing the course you'll gain a certificate and 16 CPD points. The training helps you to generate your own comprehensive course notes and will leave you with a thorough understanding of how to implement the ISO 13485:2016 standard.

## Pedagogical objectives

- Understand and plan ISO 13485:2016 implementation
- Find ways to increase efficiency, add value and monitor supply chains effectively
- Take the first steps towards ISO 13485:2016 certification

## Skills to be acquired

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

- Define an ISO 13485:2016 QMS
- Identify the steps for defining, planning, organizing and scheduling necessary activities
- Implement an effective quality management system
- Conduct a base line review of an organization's current position with regard to ISO 13485:2016



## Targeted audience

- Anyone involved in defining, planning, or implementing an ISO 13485:2016 based quality management system
- Management representatives
- Implementation team members

## Prerequisites

There are no formal prerequisites for this course.

## Duration

2 days – 14 hours

## **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



## Agenda - Day 1

Time	Topic
08:30	Welcome, benefits to you and introductions
	Boundaries: Conflict of interest and expertise
	Course aim, learning objectives and course structure
	Fundamentals of management systems
	Fundamentals of an ISO 13485 QMS
	Overview of ISO 13485
	The purpose, structure and requirements of ISO 13485
17:00	Implementation: <ul style="list-style-type: none"><li>• Implementation process</li><li>• Implementation outline</li><li>• Gain top management commitment</li><li>• Promote awareness</li><li>• Perform gap analysis</li><li>• Review current system</li><li>• Identify risks and opportunities</li></ul>
	Close day 1



## Day 2

Time	Topic
09:00	Welcome back and review of day 1
	Develop implementation plan
	Approving the implementation plan
	Operate and assess the system
	Continual improvement
	Certification and registration
	Course review and final questions
17:00	End of 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](mailto:training.france@bsigroup.com) or **01 89 79 00 40**.