Medical Devices | Implementing ISO 13485:2016

International Training

Number of days 2

Key information about the course

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.

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Agenda

Day 1

- 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

- Implementation:
  - Implementation process
  - Implementation outline
  - Gain top management commitment
  - Promote awareness
  - Perform gap analysis
  - Review current system
  - Identify risks and opportunities
- Summary day 1

Day 2

- Welcome back and review of day 1
- Develop implementation plan
- Approve the implementation plan
- Operate and assess the system

- Continual improvement
- Certification and registration
- Course review and final questions
- End of course

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

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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

On completion of this training, participants 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

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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