ISO 13485:2016 Requirements - International

Your partner in progress

Course descriptive

This course explores the requirements of the ISO 13485:2016 Quality Management System standard, discussing key principles and how the standard interacts with ISO 9001 and the European MDR/IVDR. The relationship with ISO 14971 'Application of Risk Management to Medical Devices' is also explored during the course.

Pedagogical objectives

- Take the first steps towards ISO 13485:2016 certification
- Understand how you can better meet regulatory requirements, leading to increased patient safety
- Find ways to increase efficiency and cost savings through quality management
- Monitor supply chains to achieve continuous improvement
- Develop safe and effective medical devices

Skills to be acquired

On completion, you will be able to:

- Explain the use of ISO 13485:2016, as the basis for a quality management system for medical device organizations
- Define the overall structure of ISO 13485:2016
- Apply the process approach concept of the standard
- Recognize the key clauses of the ISO 13485:2016 standard

Targeted audience

Senior management, quality managers, regulatory affairs managers, internal and external auditors, consultants and anyone involved with the implementation of the standard.

Prerequisites

There are no formal prerequisites, however it will be useful for delegates to read the standard before attending the course.

Duration

1 day – 7 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

- Questionnary 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	Subject
09:00	Benefits to you, welcome and introductions
	Course aims, objectives and structure
	Boundaries: Conflict of interest and expertise
	Quality definitions and the process approach and documentation
	Definition of a medical device within the industry
	Introduction to ISO 13485
	Clauses 0, 1, 2 and 3
	Clauses 4 and 5
	Clause 6: Resource management
	Clause 7: Product realization… including risk management
	Clause 8: Measurement, analysis and improvement
	Reflection and feedback
17:00	Close of day

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

**Each delegate receives a training convention after the enrollment.

***Please note that for the public sessions, you have until 48h before the start of the course to confirm your enrollment. 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**.