EU Medical Device Regulation (MDR) 2017/745 QMS Auditor - International

Your partner
in progress

Course descriptive

The Medical Device Regulation (MDR) is the legislation detailing the requirements that manufacturers must meet to place medical devices on the market in the European Union.

As more and more manufacturers now have their MDR Quality Management System (QMS) certificates, it's imperative for continued compliance that they are able to perform audits against the requirements of the QMS MDR.

This course is designed to give you insights into how Notified Bodies may perform an MDR QMS compliance audit, using the topics of a typical MDR audit agenda as the basis. This will enable you to optimize your auditing skills and knowledge to boost your audit capabilities, gain confidence in planning and performing an effective EU MDR QMS audit, as well as ensuring continued compliance to the EU MDR (2017/245).

Pedagogical objectives

- Perform audits against the EU MDR (2017/245) Quality Management System requirements
- Ensure continued compliance against the EU MDR (2017/245) QMS requirements
- Be confident that your organization can rely on competent EU MDR (2017/245) auditors

Skills to be acquired

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

- Establish the relationship between the ISO 13485:2016 and the EU MDR (2017/745)
- Recognize and interpret the key QMS requirements of the EU MDR (2017/745)
- Appreciate that the range of medical device classifications mean differing requirements in the context of auditing
- Plan for and conduct EU MDR (2017/745) QMS audits to establish and maintain compliance against these requirements
- Report on any identified nonconformities

Targeted audience

- RA, QM, and QA professionals who already perform audits
- Anyone concerned with certification or active in projects for CE-marking, especially involved in the QMS implementation side
- Staff involved in audits and working for organizations that partner with Medical Device manufacturers e.g. as subcontractor, crucial supplier, OEM, Authorized representative, importer, distributor, auditee

Prerequisites

Already a competent auditor in the medical device industry and especially familiar with the auditing requirements of ISO 13485:2016.

You must have a good understanding of the requirements of the MDR. You should also have experience with quality management systems for the medical device industry. Recommended to have either attended the ISO 13485 Lead auditor or ISO 13485 internal auditor course.

Duration

3 days – 21 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
09:00	Welcome, course structure, agenda, and benefits to you
	Boundaries: Conflict of interest and expertise, introductions, course aim, learning objectives and training modules
	Module 1: General introduction: MDR QMS requirements and EN ISO 13485:2016
	Module 2: Strategy for regulatory compliance
	Module 3: Identification of general safety and performance requirements
	Module 4: Resource management and communication: Person responsible for regulatory compliance and economic operators
16:30	Day 1 review and close of the day

Day 2

Time	Topic
09:00	Welcome and recap from Day 1
	Module 4: Resource management and communication: Person responsible for regulatory compliance and economic operators
	Module 5: Risk management
	Module 6: Clinical evaluation
	Module 7: UDI system and assignment
	Module 8: Post-market surveillance system and post-market clinical follow-up
16:30	Day 1 review and close of the day

Day 3

Time	Topic
09:00	Welcome and recap of Day 2
	Module 9: Device vigilance system
	Module 10: Design of devices and design changes
	Module 11: Labeling and summary of safety and clinical performance
	Module 12: Technical documentation assessment
	Module 13: Course review and summary
16:00	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 or **01 89 79 00 40**.