
# Medical Devices | EU medical Device Regulation (MDR) 2017/45 - QMS Auditor

International Training

**Number of days** 3

## Key information about the course

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).

# International training - EU QMS Auditor

## Agenda

### Day 1

- 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
- Day 1 review and close of day

### Day 2

- 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
- Day 2 review and close of day

### Day 3

- 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
- End of course

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

# International training - EU QMS Auditor

## 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

On completion of this training, participants 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

## 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

bsi.

# International training - Internal Auditor ISO 13485:2016

**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.

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**

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