BSI Training Academy

Implementation of the Medical Device Regulation (MDR) for CE marking training course

Essential information about the three-day course

This training course aims to offer guidance on implementation of the requirements stipulated in the Medical Devices Regulation (MDR). It focusses on enabling you to draw up a clear concept or project plan, and how to integrate the requirements into your business and your documentation. Moreover, you should gain confidence and expertise to evaluate and implement more specific requirements on your own.

The MDR is the legislation detailing the requirements that manufacturers have to meet to place medical devices on the market in the European Union.

The MDR focusses on device safety and performance, emphasizing pre-market requirements, conformity assessment, quality management aspects, post-market-surveillance (PMS), transparency and traceability.

The Regulation will affect all medical device manufacturers, importers, distributors and EU Representatives. Subcontractors/suppliers will also be affected, as will manufacturers of some devices without a medical purpose (for example, devices used for esthetical body modification, or contact lenses to change eye colour without correcting vision).

Our course agenda

Day 1

- Boundaries: Conflicts of interest and structure
- General obligations
- Scope of the MDR
- Determine risk class and applicable 'NBOG' codes
- Select conformity assessment procedure
- Amend and maintain QMS
- Identify applicable safety and performance requirements

Day 2

- Continuation of applicable safety and performance requirements
- Technical documentation best practice
- Apply conformity assessment procedure

Day 3

- Assign Unique Identifications
- Complete DoC (Declaration of Conformity) and affix CE mark
- Post Market Surveillance (PMS)
- review of course

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On completion, you will be awarded an internationally recognized BSI Training Academy certificate

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...making excellence a habit.™

Implementation of the Medical Device Regulation (MDR) for CE marking training course

This three-day training course will help you to implement the requirements of European Medical Device Regulation (MDR) to obtain and maintain CE marks for your product, giving you access to a market with 500+ million people.

Make sure this is the right course for you.

Who this course is for:

This course is especially suitable for:

- RA, QM, and QA professionals who need to implement the MDR
- Anyone concerned with certification or active in projects for CE marking
- Employees working for organizations that partner with Medical Device manufacturers e.g. as subcontractor, crucial supplier, OEM, authorized representative, importer, distributor, auditee

What you'll learn:

By attending this course, you'll be able to:

- Evolve a strategy for regulatory compliance as stipulated by MDR
- Implement requirements concerning conformity assessment
- Fulfil technical documentation requirements
- Plan post-market activities required by MDR
- Put into effect your knowledge of implementation of MDR requirements into your organization, e.g. in projects for CE marking

Benefits:

This course will enable you to:

- Implement the requirements of the European Medical Devices Regulation
- Guide and support other people and partner organizations affected by MDR
- Set up and update required documentation
- Take the necessary steps for your organization to meet the MDR requirement
- Maintain compliance to MDR and other/future documents related to Medical Device legislation
- Systematically explore and implement more detailed and updated provisions (e.g. common specifications (CS), delegating and implementing acts, standards)

Please note: This course will not cover implementation for In Vitro Diagnostics or concentrate on devices with specific requirements.

Why train with BSI?

Our high impact accelerated learning approach increases learning by improving knowledge retention and skill application. This course is activity-based, resulting in a deeper understanding of the material and a greater impact on job performance.

Prerequisites

You must have a good understanding of the requirements in the MDR, which is conveyed by our one-day Requirements training course or our MDD to MDR transition course. You should also have either:

- Experience with, or basic knowledge of quality management systems for the medical device industry
- A good understanding of European Medical Device legislation
- Some experience in pre- or post-market activities within the EU

Next steps with the BSI Academy

Want to learn more? You may also be interested in:

- IVDR courses
- Specific courses on clinical evaluation and risk management
- MDR one-day course
- MDD to MDR transition course

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