BSI Transitions

Medical Devices Regulation

BSI Akademie

Implementation of Medical Device Regulation (MDR) for CE marking

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

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, contact lenses to change eye colour without correcting vision, etc.).

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 requirements will also affect (supplier) audits and governmental control, introduce new partners to interact with, and increase communication needs and obligations (e.g. contracts, reporting, documentation, and publication of information).

This course aims to offer guidance on implementation of the requirements stipulated in the 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.

What will I learn?

- Evolve a strategy for regulatory compliance as stipulated by MDR
- Implement requirements concerning the following steps for Conformity Assessment:
  - Scope and applicability of MDR
  - EU risk classification criteria for medical devices to determine "Risk Class"
  - General Safety and Performance Requirements (GSPRs) as the basis for CE marking, including the use of standards
  - conformity assessment routes and their application based on risk class
  - self-certification, CE-certification by Notified bodies, involvement of authorities, scrutiny
  - 'Declaration of Conformity' and CE marking
- Fulfil Technical Documentation requirements
- Plan post-market activities required by MDR
- Put into effect gained knowledge concerning implementation of MDR requirements into your organization, e.g. in projects for CE-marking

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...making excellence a habit.™

Make sure this is the right course for you.

Who should attend?

The course is especially suitable for:

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

What will I gain?

- 3 days
- Detailed course notes and lunch are provided.

On completion, you'll be awarded an internationally recognized BSI Training Academy certificate. .

How will I benefit?

This course will help you:

- 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

Why invest in training from BSI?

BSI training courses are delivered by experts with experience in the subject. They're truly passionate about sharing their knowledge and ensuring you learn. Trusted experts with years of hands-on and business experience, they bring the subject matter to life with relevant and contemporary examples.

Upon successful completion of your course, you'll receive an internationally recognized BSI certificate.

Training delivered at your site

This could be a convenient and cost effective option, especially if you have multiple delegates. Talk to one of our experts to find out more.

Next steps with the BSI Academy

Want to learn more? You may be interested in:
ISO 13485 Transition courses
MDSAP: Fundamentals and Readiness

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