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Medical Devices Regulation

Requirements

One Day

Learn about the key requirements, concepts, and the overall process for CE marking under the Medical Devices Regulation (MDR). The CE mark gives access to a market with 500+ million people.

The Medical Devices Regulation 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 well as 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 conveys key concepts of the European Medical Devices Regulation (MDR). All Medical Devices will need to undergo a Conformity Assessment Procedure based on the MDR requirements in order to be placed on the European Union market. You will gain understanding of the requirements stipulated within MDR.

The course will give you an understanding of the key requirements, which will provide:

- Essential knowledge to understand Regulatory Affairs of Medical Devices in EU, e.g. in the position of top management, or a manager or project member in QM/QA, R&D, design, manufacturing, Supply Chain, Customer service and sales.
- The ability to understand the demands of the subcontractor, supplier, OEM, authorized representative, importer, distributor, allowing better relationships between them and the legal manufacturer
- A basis to learn later-on about implementation of CE-marking projects

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How will I benefit?

This course will help you:

- Understand the key requirements and concepts of the European Medical Devices Regulation
- Communicate the impact of the key requirements introduced by the MDR to your organization

Who should attend?

The course is especially suitable for

- New starters in Regulatory Affairs (RA), personnel increasing their responsibility in this area, and RA professionals who are not familiar with the European MDR
- Personnel working with Regulatory Affairs departments, e.g. top management, manager or project member in QM/QA, R&D, Design, manufacturing, Supply Chain, Customer service and sales.
- Staff working for organizations that partner with Medical Device manufacturers , e.g. as subcontractor, supplier, OEM, Authorized representative, importer, distributor, auditee

Please note: This course will not cover In Vitro Diagnostic Devices. Please refer to the 'Related training' below if you need more detailed information e.g. for implementation.

What will I learn?

By the end of the course delegates will be able to:

- Communicate the key requirements and concepts within the Regulation
- Reference the necessary aspects to evaluate if and how your company is affected by MDR and to what extent (e.g. what products, roles, activities)
- Understand the vocabulary used within MDR
- Explain the structure and administration of the Regulation
- Recognize partners of manufacturers affected by the Regulation
- Describe key steps of Conformity Assessment
- Explain the main impacts on the QMS relating to MDR
- Understand requirements for Post-Market Surveillance and updates
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There are no formal prerequisites for this course, but participants will benefit from a basic knowledge of Medical Devices use, design, or manufacture and/or general understanding of quality management.

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.

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

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