BSI Training Academy

Requirements of the Medical Device Regulation (MDR) training course

Essential information about the one-day course

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.

This course conveys key concepts of the European 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'll gain understanding of the requirements stipulated within the MDR.

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

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 (supply chain) audits and governmental control; introduce new partners to interact with, and increase communication needs and obligations (for example: contracts, reporting, documentation, and publication of information).

Our course agenda

- Introduction to CE marking and European legislation, and general obligations under the MDR
- Scope of the MDR
- Determine risk class of device
- Select conformity assessment procedure
- Amend and maintain a QMS
- Identify applicable safety and performance requirements
- Assemble Technical Documentation
- Apply conformity assessment procedure and assign unique identifications
- Complete Declaration of Conformity (DoC) and affix CE mark
- **Post-market surveillance (PMS)**
- Transition arrangements

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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.™

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This course will give you an understanding of the key requirements, which will provide essential knowledge to understand Regulatory Affairs of medical devices in the EU. It's relevant to top management, managers or project members in quality management, quality assurance, research and development, design, manufacturing, supply chain, customer services and sales.

It will give you the ability to understand the demands of the subcontractor, supplier, original equipment manufacturer, authorized representative, importer and distributor, allowing better relationships between them and the legal manufacturer. It also forms a basis on which to learn later about the implementation of CE marking projects.

Make sure this is the right course for you.

This course is for:

- New starters in Regulatory Affairs (RA) and those increasing their responsibility in this area, and RA professionals who are not familiar with the European MDR
- Anyone 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 etc.

What you'll learn:

You'll be able to:

- Communicate the key requirements and concepts within the Regulation
- Reference aspects and evaluate if and how your company is affected by the MDR and to what extent
- Explain the structure and administration of the Regulation
- Recognize partners of manufacturers affected by the Regulation
- Describe the key steps of a conformity assessment
- Explain the main impacts on the QMS relating to the MDR
- Recognize the requirements for PMS and updates

Benefits:

This course will help you:

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

Please note: This course will not cover In-Vitro Diagnostic Devices.

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

There are no formal prerequisites for this course, but you will benefit from a basic knowledge of medical devices use, design, or manufacture and / or a general understanding of quality management

Next steps with the BSI Academy

Want to learn more? You may also be interested in

- ISO 13485 courses
- Implementation of the MDR course
- Clinical evaluation and risk management course
- MDD to MDR transition course

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