BSI Akademie

Medical Devices Regulation

MDD to MDR

One Day

Learn about the key changes to requirements for CE marking following the publication of the new Medical Devices Regulation (MDR). The changes will affect all medical device manufacturers, importers, distributors and EU Representatives. Manufacturers of some classes of devices without a medical purpose (for example, devices used for body modification, contact lenses to change eye colour without correcting vision, etc.) will also be affected.

The Medical Devices Regulation has replaced the Medical Devices Directive (93/42/EEC) as the legislation detailing the requirements which manufacturers have to meet to place medical devices on the market in the European Union. Publication of the text in spring 2017 marked the start of a three year transition period for manufacturers to meet the new requirements.This long awaited text brings with it more scrutiny of technical documentation; it addresses concerns over the assessment of product safety and performance by placing stricter requirements on clinical evaluation and post-market clinical follow-up, and requiring better traceability of devices through the supply chain.

This course introduces you to the key changes from the European Medical Devices Directive (MDD) to the new European Medical Devices Regulation (MDR). All Medical Devices and identified devices without a medical purpose will need to undergo a Conformity Assessment Procedure based on the new MDR requirements, in order to place devices on the European Union market. The course will give a general guideline of how to approach application of the new MDR, and will highlight the differences to the MDD that will affect all manufacturers.

The new requirements will also have implications relating to an organization's Quality Management System (QMS), specifically: Auditing, requirements for clinical evaluation and technical documentation, post-market surveillance, vigilance reporting, and accessibility of information across European member states, as well as to the public and end users.

Please note: This course does not focus on mapping the AIMD to the MDR, however, the course will provide value to AIMD clients by looking at the new Regulation and how to transition to the MDR. It will also not cover In Vitro Diagnostic Devices.

Book now bsigroup.de/akademie/medical-device
or give us a call +49 (0) 69 2222 89 299

bsi.

...making excellence a habit.™

BSI Akademie

How will I benefit?

This course will help you:

- Understand the key changes in the transition from the Medical Devices Directive to the new European Medical Devices Regulation
- Communicate the impact to your organization of the key changes introduced by the MDR, and the transition arrangements defined within the MDR
- Identify the next steps for your organization to meet the MDR requirement

Who should attend?

Manufacturers of Medical Devices, especially: Regulatory Affairs, Design and Development, Clinical Affairs Specialists, Quality Management, and Quality Assurance personnel.

Please note: This course does not focus on mapping the AIMD to the MDR, however, the course will provide value to AIMD clients by looking at the new Regulation and how to transition to the MDR. It will also not cover In Vitro Diagnostic Devices.

What will I learn?

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

- Explain the changes in the structure and administration of the Regulation
- Recognize new economic operators affected by the Regulation
- Identify key changes to the requirements concerning the following steps for Conformity Assessment:
    - Check Device is within Scope of MDR
    - Determine 'Device Class'
    - Select 'Conformity Assessment Procedure'
    - Identify Applicable 'Safety and Performance Requirements'
    - Assemble 'Technical Documentation'
    - Apply Conformity Assessment Procedure
    - Assign UDI
    - Complete 'Declaration of Conformity'
    - Affix 'CE Mark'
    - Post-Market Surveillance and Updates
- Explain the main impacts on the QMS relating to the above steps, including:
    - Frequency, extent and conduct of audits
    - Electronic data management and public access to data
    - Clinical investigations, clinical evaluation and post-market surveillance
    - Roles of commercial partners
- Communicate the transition arrangements as stipulated within the Regulation

Book now
bsigroup.de/akademie/medical-device

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.