Medical Devices | Medical Device Directive (MDD) to medical Device Regulation (MDR)

International Training

Number of days **3**

Key information about the course

This course introduces you to the key changes from the European Medical Device Directive (MDD) to the new European Medical Device 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.

International training - MDD to MDR

Agenda

Day 1

- Benefits to you, welcome and introductions
- Boundaries: Conflict of interest and expertise
- Course aim, learning objectives and course structure
- Changes in the structure and administration of the Regulation
- New economic operators affected by the Regulation
- Scope of the MDR
- Determine risk class of device
- Select conformity assessment procedure
- Identify applicable safety and performance requirements
- Assemble technical documentation
- Apply confomity assessment procedure
- Assign Unique Device Identification (UDI)
- Complete Declaration of Conformity (DoC)
- Affix CE mark
- Post-market surveillance (PMS)
- Transition arrangements
- Reflection and feedback
- Close of day

International training - MDD to MDR

Pedagogical objectives

- Understand the key changes in the transition from the Medical Devices Directive to the new 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

Targeted audience

- Manufacturers of medical devices, especially: Regulatory Affairs, Design and Development, Clinical Affairs Specialists, Quality Management, and Quality Assurance personnel.

Skills to be acquired

- 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 the scope of the MDR
- Determine risk class of device
- Select conformity assessment procedure
- Identify applicable safety and performance requirements
- Assemble technical documentation
- Apply conformity assessment procedure
- Assign unique device identification (UDI)
- Complete Declaration of Conformity (DoC)
- 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

International training - MDD to MDR

Pedagogical, technical and framing means

Course materials including:

- Introduction to the training, detailed program and security assignments
- Course presentation, theory and activities/ role plays
- Answers to the activities
- Videos
- Additional documents, distributed during the sessions, to use for the activities
- Attendance sheet to be signed

Assessment specifics

- Questionnaire to assess the knowledge at the end of the training
- Customer survey

What is included ?

- Course materials, provided electronically
- Letter of attestation
- Official certificate

Prerequisites: You should have a good understanding of the existing Medical Devices Directive (93/42/EEC).

These training modules are eligible to the subsidizing by the public institutions in France (OPCO);

Each delegate receives a training convention after the enrollment.

Please note that for the public sessions, you have until 48h before the start of the course to confirm your enrollment. For the in-house sessions, the deadline would be of two weeks prior to the start of the course.

Should you be in a disabled situation, please contact us and indicate what details should be taken into account.

You can contact us on **training.france@bsigroup.com** or **01 89 79 00 40**

Contact us:

Phone: **+33 (0)1 89 79 00 40**

Email : **training.france@bsigroup.com**

Website : **bsigroup.fr/nos-services-formation**

bsi.