Medical Devices | Technical Documentation for the Medical Device Regulation

International Training

Number of days **1**

Key information about the course

A required part of conformity assessment and CE Marking is the need for technical documentation which includes the collation of supporting information about your medical device.

Technical documentation is maintained throughout the product lifecycle. Learn how to assemble this and other types of required information so you can CE Mark your device in Europe.

International training
Technical Documentation for the MDR

Agenda

Day 1

- Welcome, benefits and introductions
- Course aims, objectives and structure
- Technical documentation: conformity assessment, overview and contents
- MDR Annex II:
    - Section 1: Device description and specifications, including variants and accessories
    - Section 2: Information to be supplied by the manufacturer
    - Section 3: Design and manufacturing information
    - Section 4: General safety and performance requirements
    - Section 5: Benefit-risk analysis and risk management
    - Section 6: Product verification and validation
- MDR Annex III:
    - Section 1: Technical documentation on post-market surveillance
- MDR Annex XIV:
    - Part A: Clinical evaluation
    - Part B: Post-market clinical follow-up
- MDR Annex IV: Declaration of conformity
- Technical documentation summary
- Guidance documents: Technical documentation structures
- Course summary and final questions

Once you have completed the training, you will receive a BSI training certificate.

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Pedagogical objectives

- Ensure auditable technical documentation meets regulatory requirements and demonstrates product safety and performance
- Reduce delays to product certification by providing complete and compliant documentation
- Reduce costs by reducing audit questions and nonconformities, thereby streamlining the certification process

Skills to be acquired

On completion of this training, you'll be able to:

- Confirm the technical documentation requirements as specified in the MDR and relevant guidance documentation
- Interpret the MDR in relation to the technical documentation requirements
- Define the process enabling the creation and maintenance of compliant technical documentation
- Grasp how standards and guidance can be used to improve your technical documentation
- Recognize what is expected by Notified Bodies for technical documentation during reviews and be better prepared
- Recognize the documentation requirements during the product lifecycle and the post-market updates needed

Targeted audience

QA/Regulatory personnel involved in compiling technical documentation; product design personnel and those in research and development for medical devices intended for the European market.

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

International training - Technical Documentation for the MDR

Prerequisites: You should have a basic understanding of European Medical Device Regulation (MDR)

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**

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