Medical Devices | Implementation of MDR for CE Marking

International Training

Number of days 3

Key information about the course

This three-day course from your partner in learning is especially useful for regulatory affairs, quality management and quality assurance professionals who need to implement the medical device regulation (MDR). The MDR training is also designed for people working for organizations that partner with Medical Device manufacturers.

You will learn all the requirements needed for conformity assessment, how to fulfill technical documents and how to plan post-market activities required by the MDR. By the end of the course you will be able to put all this knowledge into working practice in your organization.

International training - Implementation of MDR for CE Marking

Agenda

Day 1

- Benefits to you, welcome and introductions
- Boundaries: Conflicts of interest and expertise
- Course aims and objectives
- **Course content and structure**
- Some regulatory background
- General obligations
  - Who is responsible?
  - Items for technical documentation
  - Conformity assessment
- Medical Device Regulation 2017/745
  - Scope of the MDR
  - Relation of the MDR to other Union legislation
  - Definition: Medical device and accessories
- Device risk classification
  - Determine risk class and applicable MDR codes
  - 22 rules in the MDR: Annex VIII
  - Applying the rules
- Conformity assessment options
  - Select conformity assessment procedure
  - Conformity assessment routes
- Quality Management System
  - Amend and maintain QMS
  - ISO 13485: A stairway to MDR
- General Safety and Performance Requirements (GSPRs)
  - Identify applicable safety and performance requirements continued
- Day 1 review and questions

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Day 2

- Welcome to day 2
- Lifetime and life cycle
  - How long must devices stay safe and effective?
  - Life cycle
- Risk management
  - Risk management process
- GSPRs
  - Annex I – General safety and performance requirements
  - Checklist and compilation of evidence for demonstration of conformity of GSPRs
- Labelling and symbols
  - Labelling: A selection of issues
  - Instruction for Use (Ifu): A selection of issues
  - Pillars of the technical documentation
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- Technical documentation
  - Content of technical documentation under the MDR
  - Design and manufacturing information
  - Product verification and validation
- Clinical evaluation
  - Clinical requirements under the MDR
  - Clinical development plan
  - Some issues with clinical data
- Clinical investigations
  - Requirements for clinical investigations
  - Summary of safety and performance (SSCP)
  - Competence of persons and authors
- Conformity assessment audits by Notified Bodies
  - Apply conformity assessment procedure
  - Technical sampling by NBs
- Day 2 review and questions
- Close of the day

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Day 3

- Welcome to day 3
- Technical documentation
  - Submission of technical documentation
  - Surveillance of technical documentation
  - Official language(s) determined by member state concerned
- Significant changes
  - Evaluation of changes as significant
- Strategy for regulatory compliance
- UDI, SRN and EUDAMED
  - Assign unique identifications
  - SRN
  - UDI
  - EUDAMED
- Declaration of conformity and CE marking
  - Complete declaration of conformity and affix CE Mark
  - Where does the CE mark appear?
  - CE mark is prohibited for
- Post-market Surveillance (PMS)
  - Periodic Safety Update Report (PSUR)
  - What is PMS good for?
  - Alarming issues
  - When is an incident serious?
- Vigilance
  - Vigilance reporting
  - Actions of competent authorities after report
  - Who cooperates in FSCA (Field Safety Corrective Action)?
- Recap and transition arrangements
- Review of course and final questions
- End of course

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

International training - Implementation of MDR for CE Marking

Pedagogical objectives

- Implement the requirements of the European Medical Devices Regulation
- Guide and support other people and partner organizations affected by MDR
- Set up and update required documentation
- Take the necessary steps for your organization to meet the MDR requirement
- Maintain compliance to MDR and other/future documents related to Medical Device legislation
- Systematically explore and implement more detailed and updated provisions (e.g. common specifications (CS), acts, standards)

Targeted audience

- RA, QM, and QA professionals who need to implement the MDR
- Anyone concerned with certification or active in projects for CE-marking
- Staff working for organizations that partner with Medical Device manufacturers e.g. as subcontractor, crucial supplier, OEM, Authorized representative, importer, distributor, auditee

Skills to be acquired

- Develop a strategy for regulatory compliance as stipulated by MDR
- Implement requirements concerning the following steps for Conformity Assessment:
- Scope and applicability of MDR
- EU risk classification criteria for medical devices to determine "Risk Class"
- General Safety and Performance Requirements (GSPRs) as the basis for CE marking, including the use of standards
- Conformity assessment routes and their application based on risk class
- Self-certification, CE-certification by Notified bodies, involvement of authorities, scrutiny
- 'Declaration of Conformity' and CE marking
- Fulfil Technical Documentation requirements, e.g. in
- Putting together 'Technical Documentation'
- Necessary control of outsourced activities and processes and roles of external partners (e.g. supplying and commercial)
- Instantiate the importance and role of clinical data
- Risk management, process validation and their regulatory significance
- Drawing up Instruction For Use, label and other information supplied with the device
- Consistency and validity of information and electronic data management
- Plan post-market activities required by MDR with respect to:
- Risk Management and related planning
- Post-Market Surveillance and Post-Market Follow-Up (PMCF)
- Periodic reports, Vigilance, ad-hoc reporting
- Regulatory responsibilities of all economic operators including communication with competent authorities, notified bodies, economic operators, customers etc.
- Recall, Field Safety Corrective Actions (FSCA), Corrective And Preventative Action (CAPA)
- Regulatory relevance of change control to QMS, design and manufacturing
- Extent of readiness for audits/ reviews/assessment
- Put into effect gained knowledge concerning implementation of MDR requirements into your organization, e.g. in projects for CE-marking

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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 must have a good understanding of the requirements in the MDR, which is conveyed by our one-day Requirements training course or our MDD to MDR transition course.

You should also have either experience with, or basic knowledge, of quality management systems for the medical device industry, or good understanding of European Medical Device legislation, or some experience in pre or post-market activities within the EU.

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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