Requirements of the MDR for CE Marking - International

Your partner
in progress

Course descriptive

This one-day medical device training outlines the key requirements, concepts and overall process for CE marking under the medical device regulation. It's suitable for anyone working in regulatory affairs/quality assurance or staff partnering with medical device manufacturers.

This stage of your learning journey creates a solid base for implementing your own CE marking projects. It provides essential knowledge about EU medical devices and regulatory affairs from all areas of an organization. It also explains the demands that fall on subcontractors, importers and distributors.

After completing this medical device training, you will have a sound understanding of the medical device regulation and be able to communicate it to others. You will also gain eight CPD points and take away comprehensive training course notes.

Pedagogical objectives

The course will give you an understanding of the key requirements, which will provide:

- Essential knowledge to understand Regulatory Affairs of Medical Devices
- in EU, e.g. in the position of top management, or a manager or project
- member in QM/QA, R&D, design, manufacturing, supply chain, customer service and sales
- The ability to understand the demands of the subcontractor, supplier, OEM, authorized representative, importer, distributor, allowing better relationships between them and the legal manufacturer
- A basis to learn later about implementation of CE-marking projects

Skills to be acquired

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

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

Targeted audience

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

Prerequisites

There are no formal prerequisites for this course.

Duration

1 days – 7 hours

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

Agenda - Day 1

Time	Topic
09:00	Benefits to you, welcome and introductions
	Boundaries: Conflicts of interest and structure
	Course aims and objectives
	Introduction to CE and European legislation • What is CE Marking? • Responsibilities of key players • MDR responsibilities
	General obligations under MDR • Manufacturers' responsibilities
	Scope of the MDR • Definition • Relation to other EU Directives/Regulations
	Determine risk class of device • Risk-based classification • Classification rules
	Select conformity assessment procedure • Quality system assessment
	Amend and maintain QMS • ISO 13485 • Harmonised standards • Common Specifications
	Identify applicable safety and performance requirements • Risk management process • Information supplied with the device

Day 1

Time	Topic
	Assembling Technical Documentation • Content of Technical Documentation under the MDR • Clinical evidence and clinical evaluation
	Apply conformity assessment procedure
	Assign unique identifications • EUDAMED • SRN • UDI Types
	Complete Declaration of Conformity (DoC) and affix CE mark
	Post-market surveillance (PMS)
	Transition arrangements
	Course review and final questions
17:00	Close of day

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

**Each delegate receives a training convention after enrolment.

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