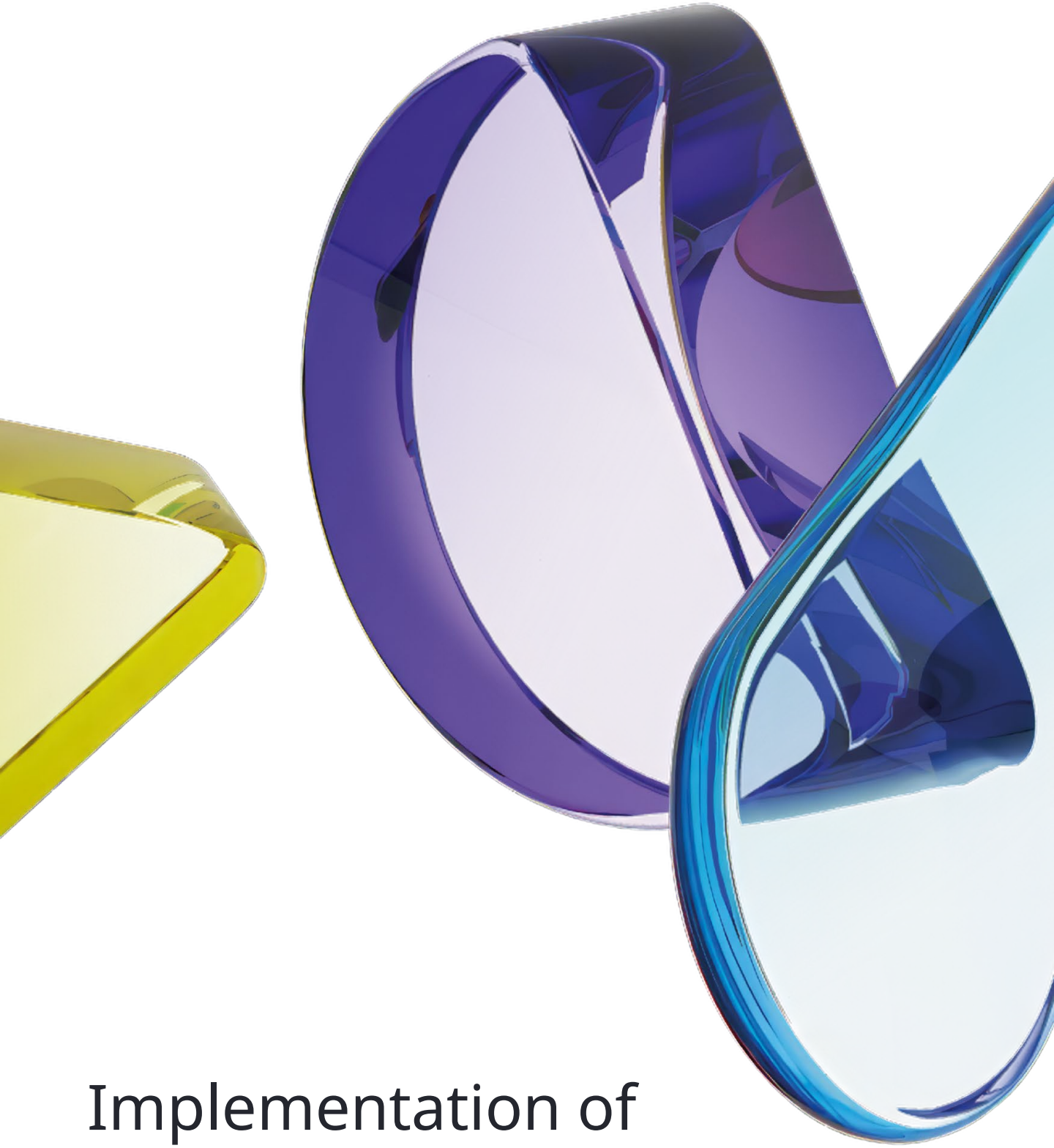

Implementation of MDR for CE Marking - International

Your partner
in progress

Course descriptive

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.

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)

Skills to be acquired

Upon completion of this training, delegates will be able to:

- 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

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

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.

Duration

3 days – 21 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 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
17:00	Summary and course end

Day 2

Time	Topic
09:00	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
	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
17:00	Close of day

Agenda - Day 1

Time	Topic
09:00	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
17:00	End of course

*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**.