Medical Devices | Requirements of the In Vitro Diagnostic Regulation

International Training

Number of days 1

Key information about the course

Learn about the key requirements of the new In Vitro Diagnostic Regulation (IVDR EU 2017/746), published in Spring 2017 with a five-year transition period.

To CE mark an IVD in Europe it will soon be mandatory to conform to this Regulation. The Regulation will affect all In Vitro Diagnostic device manufacturers, importers, distributors, and EU Representatives.

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Agenda

Day 1

- What is an IVD?
- Benefits to you, welcome and introductions
- Course aims, objectives and structure
- CE marking approach for IVD's and an introduction to the key players in the IVDR
- Classify IVD devices
- Conformity assessment routes
- Role of the General Safety and Performance Requirements as a basis for CE Marking
- Technical documentation
- Product claims, labeling, UDI and EUDAMED
- Requirements of performance evaluation
- Post-market surveillance and vigilance
- Course review and reflection
- Close of day

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

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Pedagogical objectives

- Identify the key requirements of the In Vitro Diagnostic Regulation
- Interpret and communicate the key requirements and expectations of the IVDR to your organization
- Identify the next steps in planning of product realization and commercialization in conformity with the IVDR

Skills to be acquired

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

- Identify devices that are within scope of the Regulation
- Understand the roles and responsibilities of the different Economic Operators identified by the Regulation
- Identify other key players and their obligations under the Regulation
- Identify key requirements concerning the following steps for conformity assessment:
- Determine the risk class of IVD
- Select conformity assessment procedure
- Identify applicable General Safety and Performance Requirements (GSPRs)
- Recognise key elements of Technical Documentation
- Appreciate the importance of product claims, labelling, Unique Device Identification (UDI) and EUDAMED (The European Database on Medical Devices)
- Identify requirements of clinical evidence
- Post-Market Surveillance and updates

Targeted audience

Manufacturers of In Vitro Diagnostic devices, in particular those who have not yet placed an IVD on the market in the EU, especially: Regulatory Affairs, Design and Development, Clinical Affairs Specialists, Quality Management, Quality Assurance personnel, and other Economic Operators including manufacturers, importers, distributors and authorized representatives who are new to, or have little familiarity with, the EU IVD market.

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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: There are no formal prerequisites for this course

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

Each delegate receives a training convention after the 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 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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