Medical Devices | Implementation of the In Vitro Diagnostic Device Regulation for CE Marking

International Training

Number of days 3

Key information about the course

The In Vitro Diagnostic Devices Regulation (IVDR 2017/746) is the legislation detailing the requirements which manufacturers have to meet to place in vitro diagnostic devices on the market in the European Union.

The Regulation contains detailed requirements that need to be implemented, and will affect all IVD manufacturers, importers, distributors and EU Representatives.

The IVDR focuses on devices to be safe and effective, emphasizing pre-market requirements, conformity assessment, post-market-surveillance (PMS), and traceability.

This course aims to offer guidance on implementation of the requirements stipulated in the IVDR into your business.

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Agenda

Day 1

- Benefits to you, welcome and introductions
- Boundaries: Conflicts of interest and expertise
- Course aims, structure and objectives
- What is an IVD?
- EU Single market and the IVDR
  - Journey to the IVD Regulation
  - Advantages of the changes
  - Delegated and implementing acts
  - Structure of the IVDR
- Responsibilities
  - Economic operators
  - Who gets an SRN?
  - Person responsible for regulatory compliance
  - Notified bodies
  - Competent authorities
  - Others in supply chain
- Placing on the market
  - Putting into service
- Harmonized standards and common specifications
- CE mark
- Risk-based classification
  - Intended users and test
  - Classification of controls
  - Classification dispute
- Conformity assessment
  - Routes of conformity
  - Sampling strategy
  - Certificate scopes
  - Certificates issued under Annexes
  - EU reference laboratories
  - Companion diagnostics
- Notified bodies and scrutiny
  - Unannounced audits
  - MDCG and regulatory operators
- Reflection and feedback
- Close of day

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Day 2

- Welcome to day 2
- Case Study business case
- GSPRs
  - GSPR Trace Matrix
  - Risk Management
  - EN ISO 14971
- Performance evaluation, clinical evidence and post-market performance follow-up
  - General requirements for performance studies
  - Clinical evidence, performance evaluation, scientific validity and analytical performance
  - Performance evaluation plans and reports
  - Summary of safety and performance
  - Post-market performance follow-up
  - Interventional and special clinical studies
- Post-market surveillance and vigilance reporting
  - Post-market activities and post-market surveillance
  - PMS Report and PSUR
  - Vigilance reporting
  - MEDDEV guidance
- End of day 2

Day 3

- Welcome to day 3
- Case study regulatory strategy
- Technical documentation
  - Expectations of the IVDR
  - Technical file review and Notified Body expectations
  - QMS technical documentation
- Product claims and labelling
  - Claims
  - Labelling
  - Symbols
  - Safety data sheets
- EUDAMED and registration
  - Annex VI Registration
  - Unique Device Identifier (UDI)
- Significant changes
- Other Directives and Regulations
- Case study: Product strategy
- Course reflection
- End of course

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Pedagogical objectives

- Take the necessary steps for your organization to meet the IVDR requirement
- Implement the requirements of the European In Vitro Diagnostics Devices Regulation
- Execute robust and compliant performance evaluation and post market follow up studies
- Guide and support other people and partner organisations affected by IVDR

Targeted audience

- RA, QM, and QA professionals who will be implementing the IVDR within their organisations
- Personnel concerned with certification or active in projects for CE-marking, including R&D scientists, production personnel, project management.
- Staff in contact with IVD Device manufacturers at companies which are partners to manufacturer, 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 IVDR
- Recognise the roles and responsibilities of Economic Operators (legal manufacturer, Authorised representative, Importer and Distributor) and other Key Players (Notified Body, Competent Authority, significant subcontractors) under the IVDR
- Explore the role of the Notified Body
- Implement requirements concerning the following steps for Placing on the Market:
  - Scope and applicability of IVDR
  - EU risk classification criteria for IVDs to determine "Risk Class"
  - General Safety and Performance Requirements as the basis for CE Marking, including the use of standards and Common Specifications
  - Risk Management and related planning
  - Technical documentation
  - Labelling and UDI
  - Conformity assessment routes and their application based on risk-class
  - Self-certification, CE-certification by Notified bodies
  - Other key Regulations and Directives
  - EUDAMED and registration
- Plan post-market activities required by IVDR with respect to:
  - Post-Market Surveillance and post-market Follow-Up
  - Periodic reports, Vigilance, ad-hoc Reporting
  - Risk management throughout the product lifecycle
  - Involvement of authorities, scrutiny
  - Notification of significant changes
- Impart knowledge concerning IVDR 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: Participants must have an understanding of the requirements in the IVDR, for example conveyed through our IVDD to IVDR transition course, or the 1 day Requirements of the IVDR training course.

Participants would benefit from an understanding of European In Vitro Diagnostic 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.

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