BSI Akademie

In Vitro Diagnostic Regulation

Implementation

3 Days

To help implement the requirements of the European In Vitro Diagnostic Device Regulation (IVDR 2017/746) to obtain and maintain the CE mark for your product. Gain confidence with the IVD classification rules and the conformity assessment routes.

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 focusses 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. Learn the importance of the General Safety and Performance Requirements in product development, and of scientifically robust performance evaluation and clinical evidence. Explore the role of risk management during product development and in post market follow up. Develop an understanding of the interface and interaction with Notified Bodies, economic operators (importers, distributors, EU Representatives) and subcontractors/suppliers, according to their obligations under the IVDR.

Book now bsigroup.de/akademie/medical-device
or give us a call +49 (0) 69 2222 89 299

bsi.

...making excellence a habit.™

BSI Akademie

How will I benefit?

This course will help you:

- 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

Who should attend?

The course is especially suitable for:

- 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

What will I learn?

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

- 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

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.

Book now
bsigroup.de/akademie/medical-device