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In Vitro Diagnostic Regulation

Requirements

1 Day

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. .

The In Vitro Diagnostic Regulation details the requirements which manufacturers have to meet to sell In Vitro Diagnostic devices in the European Union. It replaces the In Vitro Diagnostic Directive.

This course introduces you to the key requirements of the IVDR. IVDs will now be classified according to their risk using a new rule-based system. The majority of IVDs will be subjected to independent assessment of their conformity to the Regulation by a Notified Body and will require third-party certification for the first time.

The course explores the four risk classifications and the conformity assessment routes for IVDs. It defines the Technical Documentation required, and the product safety and performance expectations, including requirements on clinical evidence, Post-Market Clinical Follow-up (PMCF) and Post-Market Surveillance (PMS). Traceability of devices through the supply chain and product labelling will be reviewed during the course.

Please note: This course does not cover Medical Devices under the Medical Devices regulation (MDR EU2017/745).

Book now bsigroup.de/akademie/medical-device
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How will I benefit?

This course will allow you to:

- 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.

Who should attend?

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 authorised representatives who are new to, or have little familiarity with, the EU IVD market. .

What will I learn?

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

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On completion, you'll be awarded an internationally recognized BSI Training Academy certificate.

This course will focus on the overall new legal framework of the IVDR, and not on specific devices. Detailed course notes and lunch are provided.