BSI Transitions

In Vitro Diagnostic Regulation

BSI Training Academy

IVD Directive to IVD Regulation Transition training course

Essential information about the course

There are significant changes in the European legislation applicable to IVDs. The IVD Regulation (EU 2017/746) has replaced the IVD Directive (98/79/EC) which will impose new requirements on manufacturers and other economic operators.

This long awaited text brings a number of significant changes to the regulatory requirements for IVD manufacturers, addressing the challenges posed by the IVD Directive. The changes include a new rule-based classification system, increased scrutiny of technical documentation, and improved traceability of devices through the supply chain.

Our one day training course has been designed to introduce IVD manufacturers and other economic operators in the supply chain to the key changes to requirements for CE marking following the publication of the new IVD Regulation (IVDR).

Our expert tutors will make sure you complete the course feeling confident that you can apply the knowledge as soon as you step back inside your organization.

The course is structured to optimize your learning using our unique approach to accelerated learning, and it will consist of a blend of practical activities, group discussions and classroom learning.

Please note: **This course will not cover Medical Devices as per the Medical Devices Regulation.**

Our course agenda

This training course will cover:

- Requirements and impacts of new IVD Regulation
- Significant changes introduced by the new IVD Regulation
- Key aspects of the transition - from Directive to Regulation
- Changes to responsibilities of Economic Operators
- Revised scope, risk-based classification, and conformity assessment
- Revised clinical expectations
- Technical documentation for compliance
- New expectations for post-market activities
- Managing the transition

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...making excellence a habit.™

IVD Directive to IVD Regulation Transition training course

We want to make sure you have the best learning experience possible. That's why we offer a range of training courses from beginner to expert. We create a positive learning environment so you retain the knowledge and acquire skills that will continue to be of use beyond the course.

Make sure this is the right course for you.

This is the course for you if you are:

- A medical device manufacturer, especially if your role is in:
  - Regulatory Affairs
  - Design and Development
  - Clinical Affairs Specialists
  - Quality Management
  - Quality Assurance
- An Authorised Representative
- An economic operator, including importers and distributors
- A Consultant

What is the course like?

- One day
- Led by a BSI expert tutor
- Relaxed and comfortable learning environment
- You'll receive detailed course notes to take away

You should have a good understanding of the existing IVD Directive (98/79/EC).

How will I benefit?

- Identify the requirements of the IVDR and understand how this will impact your organization and other economic operators
- Understand the significant changes introduced by the IVDR and what won't be affected
- Learn what needs to be revised in your current arrangements to ensure compliance
- Take steps to ensure that existing products CE marked under the IVD Directive comply with the IVDR
- Create a plan for your organization to transition to the new Regulation for new IVD product development.

Why invest in training from BSI?

BSI training courses are delivered by experts with experience in the subject. They're truly passionate about sharing their knowledge and ensuring you learn. Trusted experts with years of hands-on and business experience, they bring the subject matter to life with relevant and contemporary examples.

Upon successful completion of your course, you'll receive an internationally recognized BSI certificate.

Training delivered at your site

This could be a convenient and cost effective option, especially if you have multiple delegates. **Talk to one of our experts to find out more.**

Next steps with the BSI Academy

Want to learn more? You may be interested in:

ISO 13485 Transition courses

MDSAP: Fundamentals and Readiness

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