BSI Training Academy

Performance Evaluation and Clinical Evidence for In Vitro Diagnostic devices (IVDs) training course

Essential information about the one-day course

This intensive training course will provide you with an understanding of performance evaluation for IVDs under both the IVD Directive and Regulation. You'll learn how performance fits into the product development lifecycle and IVD Regulation (IVDR) requirements for clinical evidence.

The one-day course is ideal for anyone involved in planning, conducting or documenting performance evaluation and clinical performance studies for In Vitro Diagnostic devices placed on the market in Europe.

Our course agenda

- Boundaries; conflicts of interest
- Aims, objectives, course structure and materials
- Background – what is an IVD?
- What is required for "performance" according to the directive for an IVD?
- What are the design and implement stages?
- What is performance evaluation?
- What analytical performance studies are required?
- Clinical performance regulatory and legal considerations
- Study design and protocol considerations
- Documenting a clinical evidence and maintenance schedule

Book today at bsigroup.com/training

On completion, you will be awarded an internationally recognized BSI Training Academy certificate

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...making excellence a habit.™

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Make sure this is the right course for you.

This course is for:

- Quality assurance, Regulatory, research and development scientists involved in planning, conducting or documenting performance evaluation and clinical performance studies for IVD devices in Europe

What you'll learn:

On completion of this training, you'll be able to:

- Appreciate performance evaluation and how it fits into IVD product development under the current European IVD Directive (98/79/EC)
- Grasp key definitions of performance evaluation and clinical evidence, including what is expected under the IVD Regulation (EU 2017/746)
- Appreciate how the European regulatory requirements for IVD clinical performance studies and clinical evidence have changed with the IVDR
- Apply practical considerations for study design and protocols
- Plan and document clinical evidence under the IVD Regulation; with an appreciation of how this information should be maintained throughout the product lifecycle

Benefits:

This course will help you:

- Learn what an In Vitro Diagnostic device is and what is required to demonstrate performance according to the IVD Directive (IVDD)
- Appreciate what the design and development stages are during IVD product development
- Understand performance evaluation under the IVD Directive and the definitions of performance evaluation that incorporate clinical evidence under the In Vitro Diagnostic Regulation
- Identify the analytical performance studies required
- Explore clinical performance studies including the legal and regulatory requirements and practical considerations
- Document clinical evidence and maintain the documentation throughout the life cycle of the product

Why train with BSI?

Our high-impact, accelerated learning approach increases learning by improving knowledge retention and skill application. This course is activity-based, resulting in a deeper understanding of the material and a greater impact on job performance.

Prerequisites

You will ideally have at least a basic understanding of European In Vitro Diagnostics device regulations.

Next steps with the BSI Academy

Want to learn more? You may be interested in:

- Introduction to CE Marking for the IVDD
- Application of the IVDD
- IVD Directive to IVD Regulation Transition
- ISO 13485 Medical Devices QMS

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