Application of the In Vitro Diagnostics Directive

Course Description

BSI's "Application of the In Vitro Diagnostics Directive" three day course has been designed to enable participants to explore the IVD Directive, gain a greater understanding of the requirements and thus enable IVD devices to be placed on the European market.

Participants will be able to apply the requirements of the directive to create technical documentation to support the product throughout its lifecycle.

Managers and quality/regulatory professionals responsible for all aspects of IVD CE marking as well as internal and external auditors, will benefit from attending this course.

Learning Objectives

On completion of this training, participants will be able to:

- Explain the European CE marking approach for IVD's including its legal and operational basis
- Describe the structure and scope of the IVDD including classification and conformity routes
- Apply the essential requirements including labelling and develop suitable technical documentation
- Identify the regulatory significance of risk management and process validation
- Combine knowledge gained from the course with audit qualifications to conduct compliance audits of their organization and suppliers
- Explain the role and importance of performance evaluation including application of the Common Technical Specification (CTS)
- Interpret the criteria for reporting adverse incidents under the vigilance system
- Define the manufacturers regulatory responsibilities, including reporting of changes to products and QMS system to the Notified Body.

Intended Audience

- Regulatory & quality personnel
- People new to companies or roles impacted by the IVD Directive
- Distributors of IVD's
- Own Brand labellers (OBL)
- Start-up companies
- R&D personnel
- Internal auditors.

Course Duration

Three days.

Prerequisites

Advantageous to have a basic knowledge of quality management systems for the IVD industry or experience of the manufacture, design, marketing or use of IVD devices.

How will I learn?

We use accelerated learning techniques that encourage interaction and collaboration, keep the course varied and put your learning in context. Our tutors are the best in their field and will make sure your learning needs are met. Choose between public or in-company courses tailored to your business – whatever delivers the most positive and successful outcome for you.

Where will I learn?

We deliver five star learning at first class venues. Each venue has been selected to provide the best possible learning environment so you can maximize your learning experience.

Who are we?

As an EU Notified Body, our expertise is in auditing to the requirements of the Directives. Our tutors are skilled in transferring knowledge contained within each standard to help you embed excellence within your organization. With over 65,000 clients in 150 countries worldwide, you can trust BSI to help you perform better, reduce risk and grow sustainably.

Why train with us?

We've trained and audited thousands of businesses using the same standards so we can genuinely benchmark performance. And we can take you from beginner to certification quickly then support you with follow-up courses and webinars – and all this for the price of your course.

Did you know?

Our tutors are active practitioners in their subjects, ensuring the latest developments are fully understood. We are the leaders in medical devices regulatory expertise with over 200 BSI Medical Device product and regulation experts around the world.

Next step:

To book this course, call one of our dedicated training experts on 1 800 862 6752 or book online at bsigroup.ca/training

In-company Training

Discuss your product development in confidential surroundings by opting for bespoke in-company training.

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