IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Introduction to the In-Vitro Diagnostic Regulation (IVDR)

This two-day course will clarify the requirements applicable to in-vitro diagnostic devices under the IVD Regulation (EU) 2017/746. It will highlight the major changes to responsibility and product data expectations and will review the impact to industry.

Format:
Bespoke training

CPD:
12 hours for your records (depending on your requirements)

Certificate of completion

Course Overview

The In-Vitro Diagnostic Regulation (EU) 2017/746, which came into force in May 2017 with a transition period of five years, is intended to strengthen the current approval system for in-vitro diagnostics and makes substantial changes to the existing IVD Directive (98/79/EC) legislation.

The Regulation introduces a new risk-rule classification system based on the Global Harmonization Task Force (GHTF) rules which, for the first time, takes patient impact into consideration. This will have a significant impact on all manufacturers of IVDs as about 80 per cent of all devices will now require some form of conformity assessment by a Notified Body.

This course will clarify the requirements applicable to in-vitro diagnostic devices under the new Regulation, highlight the major changes to responsibility and product data expectations and provide a thorough understanding of the impact on the industry.

Practical workshops over the two days will help consolidate the information provided.

Benefits of attending

- **Gain** a clear overview of the key requirements of the In-Vitro Diagnostic Regulation (EU) 2017/746)
- **Learn** how the new risk-based classification system impacts in-vitro diagnostic devices
- **Understand** the implications of the transition from the IVD Directive (98/79/EC) to the new Regulation
- **Discuss** key changes to manufacturer responsibilities and product data requirements
- **Discover** practical insights through interactive workshops and real-world examples

Who should attend

- Regulatory affairs personnel
- Persons responsible for regulatory compliance
- Quality assurance professionals
- Those responsible for OEM/subcontractor control of IVDs
- Economic operators, importers, distributors

Reviews

★★★★★

The presentation was outstanding. The presenters were welcoming. The session was interactive and insightful.

Vivian Ilonzeh
Director Reg Operations
Bristol Myer Squibb
Feb 5 2025

★★★★☆

Very good.

Peter Wæde Hansen
Senior International Medical Manager
Novo Nordisk AS
Feb 5 2025

★★★★★

A really good introduction, well pitched and informative

Katherine Kouwenberg
Marketing Associate
SPD Development Co.
Mar 9 2023

★★★★★

Both speakers were nothing short of impressive. Also, I am thankful they directed us to the IVDeology app, it will be most useful, particularly in team discussions and again highlights the level of service the speakers and company offer. Also, I am thankful they directed us to the IVDeology app, it will be most useful, particularly in team discussions and again highlights the level of service the speakers and company offer.

Charlotte Briggs
RA and QA Consultant
Insight Regulatory
Mar 9 2023

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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