IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Introduction to the In-Vitro Diagnostic Regulation (IVDR)

16-17 July 2025
+ 4-5 November 2025

This two-day seminar 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:
Live online

CPD:
12 hours for your records

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 seminar 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.

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

Programme

Day 1

Introduction to IVDs

- Definition of an IVD
- Why are IVDs regulated separately?
- Investigating standards and their use
- Exploring CE marking

Historical overview of the current IVD Directive (98/79/EC)

- Examining the structure and content of the IVD Directive

Introduction to IVD Regulation (EU) 2017/746

- How did we come from the Directive to the Regulation?
- Main drivers for change
- Scale of change
- Structure and Annex

Notified Bodies

- How has the role of the Notified Bodies changed under the IVD Regulation?
- Conformity assessment

IVD Regulation – key changes

- Persons responsible for regulatory compliance
- Economic operators, importers, distributors
- UDI
- Software
- Intended use/intended purpose (including an interactive workshop)
- Performance evaluation
- Clinical evidence

Compiling the technical documentation for an IVD

- Structure and content of STED
- Technical file vs design dossier

Labelling requirements and strategies

- Understanding electronic instructions for use (e-IFUs)
- Use of language and symbols
- Translation requirements
- Traceability and EUDAMED
- UDIs

Day 2

ISO 13485:2016

- Introduction to ISO 13485
- Key changes from 2012 to 2016
- Where does it fit with IVDD & IVDR?

Risk-based classification

- How are IVDs classified?

Workshop: Product classification

- Discussion on the classification of example IVDs

Risk management

- Regulatory requirements
- ISO14971
- Usability

Workshop: Risk management

Clinical evidence and common specifications

- Scientific validity vs performance evaluation

Vigilance and PMS

- Regulatory requirements
- Incident reporting/FSCA management

Case studies: Reporting/recalls

- PMS

Key timelines and practical considerations

Discussion: Preparing a roadmap for transition

Presenters

Stuart Angell

Stuart Angell

Stuart Angell is a joint director in his own consultancy specialising in global regulatory affairs strategy and compliance for in vitro diagnostics and medical devices focusing on the transition to the new IVD/Medical Device Regulations, MDSAP and ISO13485:2016.

He has over 15 years in the IVD industry and in previous roles has been responsible for designing, reviewing and maintaining regulatory frameworks for self-declared and annex list II products including technical documentation for EU and global submissions (FDA, Health Canada, TGA, Russia, Latin America). He has an excellent understanding of risk management, Post Market Surveillance (PMS) and vigilance.

Course dates

16-17 July 2025	**Live online** 09:30-16:45 **UK (London)** (UTC+01) *Course code 14870*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 11 Jun**
4-5 November 2025	**Live online** *Course code 15036*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 30 Sep**

How to book

Online:
ipi.academy/1928

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

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:

ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipiacademy.com

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipiacademy.com

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipiacademy.com