IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Introduction to the New Performance Evaluation Requirements Mandated Under the IVDR (2017/746)

4 November 2024
+ 4 March 2025, 9 July 2025, 4 November 2025

Understand the essentials of performance evaluation under the In Vitro Diagnostic Regulation (2017/746) in this comprehensive seminar. Essential for regulatory compliance and business success.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Understand where, when and how performance evaluation should be undertaken during the life cycle of an IVD device under the IVDR (2017/746).

The EU *In Vitro* Diagnostic Medical Device Regulation (IVDR) 2017/746, came into force in May 2017, with an initial transition period of five years, and an intention to strengthen the current approval system for *in vitro* diagnostics in Europe through an evidenced based Notified Body review system. A key area of change is the minimisation of self-certification, and the introduction of mandatory documentation for the planning and reporting of the manufacturer's clinical evidence to demonstrate the safety and effectiveness of the IVD device under evaluation.

This training will provide attendees with a holistic high-level view of performance evaluation, how it sits within the wider Regulation, the vital issues your organisation needs to understand to produce the relevant evidence within the terms of the new Regulation, the importance of establishing the cross-functional team needed within your organization to meet this new and demanding regulation and the role and interaction with the new Notified Bodies. It will then go on to consider the complex implications of the Regulation for overlap with the Clinical Trial Regulation (CTR) 536/2014 and Medical Device Regulation (MDR) 2017/745.

IVDeology and Management Forum have developed this training programme to provide detailed knowledge and understanding of the heavily updated area of performance evaluation within this vital new regulation and its opportunities and threats for your business.

Special offer:

Compliment your learning with our 'Deep Dive into the IVDR Annex XIII' course. This interactive training explores the nine essential documents mandated in Annex XIII, providing critical insights into performance evaluation, studies, and post-market performance requirements.

Sign up for both and get the second course at 50% off. Please contact us at info@ipi.academy to take advantage of this offer.

Benefits of attending

- **Gain** a comprehensive overview of performance evaluation within IVDR
- **Enhance** your understanding of what performance evaluation means in the context of the new European Regulation
- **Understand** the complex IVDR processes and their inter-relationships
- **Learn** how to implement the IVDR in conjunction with Notified Bodies
- **Scope** key timelines and embrace practical considerations to support delivery
- **Takeaway** deliverables and actions for your company

Who should attend?

Professionals involved in the research, development, or manufacturing of *in vitro* diagnostic medical devices, including:

- Senior management
- Regulatory affairs personnel
- Quality assurance professionals
- Product development personnel
- Project managers
- Clinical performance study personnel

Programme

Introduction to in vitro Diagnostic Regulation

- Structure of the regulation
  - Key sections relevant for performance evaluation
- Overlap with the CTR (536/2014) and MDR (2017/745)
- Notified bodies
  - What has changed?

System failures and key drivers for change

- Main drivers for change
  - Regulatory failures
- Scale of change

Intended purpose and risk-based classification

- Intended purpose/use
- Risk-based device classification
- Software

Performance evaluation and evidence collection

- Performance evaluation
- Clinical evidence
- Post-market surveillance

Key timelines and practical considerations for your company

- Timelines for clinical performance study approvals
- Notified bodies
- The EU dashboard

Actions for your company in delivering performance evaluation compliance under the IVDR

- Takeaway deliverables and actions for your company

Presenter

Jane Leadsham

Jane Leadsham is a IVD Medical Device professional with 10 years experience gained working in *in vitro* diagnostic Medical device development firstly for Novartis Pharmaceuticals, and currently as a consultant regulatory medical writer. Jane specializes in supporting IVD manufacturers to meet the performance evaluation requirements of (EU) IVD Regulation 2017/746.

Jane has held several senior R&D scientist roles for both an in vitro diagnostic manufacturer and a biotech company and completed a five-year post-doctoral research project at the University of Kent. This cross-sector industry/academia experience has provided Jane with a thorough but diverse knowledge of research, development and product commercialization.

As a consultant medical writer to the IVD industry, under the (EU) IVD Regulations 2017/746, Jane has worked on end-to-end projects, including with Notified Bodies, and successfully completed CE certification of a Class C IVD device. Jane has completed performance evaluation documents for:

- three CDx devices including preparation of documents required for interventional performance evaluation studies,
- legacy devices transitioning from IVDD to IVDR, Classes A to D, and
- new devices in Classes A to C,
- complete sample to result fully automated systems, and
- near-patient testing/point of care device

Jane has also provided training programs on the performance evaluation requirements of the (EU) IVD Regulation 2017/746 to five device manufacturers. One manufacturer, with a complex, near-patient testing, Class D device, used Jane to provide template documents and regular on-going training and support for staff to complete the performance evaluation documents themselves. Further, Jane has acted as a third-party reviewer for performance evaluation documents written by external contractors, including AI.

As a Principal Scientist, and member of a near-patient testing device development team, with Novartis Pharmaceuticals, Jane led a group of scientists in conjunction with a CRO to design, develop and manufacture a key component of a cardiac marker immunoassay within the target timeline. Jane was part of the team that planned and executed a prospective clinical trial to assess the performance of the near-patient device .

Course dates

4 November 2024	**Live online** 09:30-16:15 **UK (London)** (UTC+00) *Course code 15214*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 30 Sep**
4 March 2025	**Live online** 09:30-16:15 **UK (London)** (UTC+00) *Course code 15215*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 28 Jan**
9 July 2025	**Live online** 09:30-16:15 **UK (London)** (UTC+01) *Course code 15216*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 04 Jun**
4 November 2025	**Live online** 09:30-16:15 **UK (London)** (UTC+00) *Course code 15217*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 30 Sep**

How to book

Online:
ipi.academy/2755

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

Email:
info@ipi.academy

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

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@ipi.academy

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

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@ipi.academy