IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Deep Dive into the IVDR Annex XIII

5 November 2024
+ 5 March 2025, 10 July 2025, 5 November 2025

Explore IVDR Annex XIII in-depth, covering Performance Evaluation, Performance Studies, and Post-market Performance. Learn what information is required, where to put it, and when, with a detailed review of nine essential documents.

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.

IVDeology and Management Forum have developed a highly interactive training programme to provide a deep-dive into the nine documents mandated in Annex XIII - Performance Evaluation, Performance Studies and Post-market Performance.

We shall answer what information is required, where to put it and when. The primary documents we will review are as follows:

- Performance Evaluation Plan
- Scientific Validity Report
- Analytical Performance Report
- Clinical Performance Study Plan
- Clinical Performance Study Report
- Clinical Performance Report
- Performance Evaluation Report
- Post-Market Performance Follow-up Plan
- Post-Market Performance Follow-up Report

Special offer:

Expand your understanding of IVDR requirements by also attending our 'Introduction to the New Performance Evaluation Requirements Mandated Under the IVDR (2017/746)' course. This training provides a comprehensive overview of performance evaluation throughout the life cycle of an IVD device, essential for ensuring regulatory compliance.

Sign up for both and receive 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 documents mandated within Annex XIII of the IVDR
- **Enhance** your understanding of key concepts used within IVDR performance evaluation
- **Understand** the purpose and scope of each document and their interrelationships
- **Learn** how to draft documents to assist Notified Body reviews

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
- R&D personnel
- Clinical performance study personnel
- Pharmaceutical/CRO clinical trial managers

Programme

IVDR Introduction

- Global overview of IVD Regulation
- Performance evaluation within IVDR

Performance evaluation plan (PEP)

- What is the purpose of the PEP
- Value to the manufacturer
- When should it be written
- What should it contain

Scientific validity report (SVR)

- What is the purpose of the SVR
- Value to the manufacturer
- When should it be written
- What should it contain

Clinical performance study plan (CPSP)

- IVDR versus ISO 20916
- The types of clinical performance study
- Clinical performance studies that require application to competent authorities
- What is required in a CPSP

Performance evaluation report (PER)

- What is the purpose of the Analytical performance report (APR), Clinical performance report (CPR) and PER
- Value to the manufacturer
- When should they be written
- What should they contain

Post-market performance follow-up (PMPF)

- What is it and how should it be used
- What would a PMPF plan contain
- Notified body expectations

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

5 November 2024	**Live online** 09:30-16:15 **UK (London)** (UTC+00) *Course code 15218*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 01 Oct**
5 March 2025	**Live online** 09:30-16:15 **UK (London)** (UTC+00) *Course code 15219*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 29 Jan**
10 July 2025	**Live online** 09:30-16:15 **UK (London)** (UTC+01) *Course code 15220*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 05 Jun**
5 November 2025	**Live online** 09:30-16:15 **UK (London)** (UTC+00) *Course code 15228*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 01 Oct**

How to book

Online:
ipi.academy/2913

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

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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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