IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Deep Dive into the IVDR Annex XIII

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:
Bespoke training

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

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

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