IPI Academy

MANAGEMENT forum

Presented by
Management Forum

An Essential Overview of the Medical Device Industry

3 July 2025
+ 7 November 2025

This one-day workshop aims to give all the key information necessary to understand the regulation of medical devices and diagnostics and to appreciate the key differences from pharmaceutical regulation.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Grasp the evolving landscape of 'Life Sciences', where pharmaceuticals, medical devices, and diagnostics converge. Gain insights into combination products, companion diagnostics, digital medicines, and AI-enabled innovations.

Designed to offer a comprehensive update on the medical device industry, this training is indispensable for pharmaceutical professionals seeking insights into the intricacies of the medical device sector and its interface with pharmaceuticals. Whether you are new to medical devices or seeking a refresher on recent changes, this course equips you with essential knowledge.

Learn about the evolving regulatory landscape, including significant changes post-Brexit affecting devices and diagnostics in the UK. Our expert-led sessions address critical questions about regulatory shifts and provide a platform to navigate the complexities of this rapidly evolving sector.

Benefits of attending

- **Gain** a better understanding of the medical device industry
- **Be aware** of the changing regulatory landscape
- **Learn** about the evolving interfaces between pharmaceuticals and medical devices
- **Gain** insights into the regulation of digital medicines
- **Learn** the new rules for devices and diagnostics in the UK post-Brexit
- **Benefit** from an opportunity for your questions to be answered

Who should attend?

This course is a must for:

- Personnel from the pharmaceutical industry who want to learn more about the devices and diagnostic sectors
- All those who want to understand the interface between devices and pharmaceuticals
- Those who require a refresher on recent changes in the medical device sector

Programme

The Convergence of pharmaceuticals, medical devices and diagnostics

- What is a medical device and an In-Vtiro Diagnostic (IVD)?
- How is the device market developing?
- The emergence of the 'Life Science' industry, digital medicine and AI-enabled products
- The challenges for regulation

An overview of the MDR and IVD Directives and the regulations - Including implementation of the MDR and the IVDR

- Challenges of MDR implementation – May 2020
- Preparation for IVDR implementation

What are the Key Differences in Approach from Pharmaceuticals?

- Who are the key players?
- The role of the Competent Authority and Authorised Representative

Notified Bodies

- What is a Notified Body?
- How to work with a Notified Body

How are medical devices and IVDs evaluated?

Review and summary of role of Notified Bodies

- How to work with Notified Bodies
- Role in changes to the device post approval
- Future developments for Notified Bodies

Clinical trial requirements for medical devices

- The control of trials for MDs and IVDs
- Phased introduction of the new EU system
- Controls for combination products
- Device and IVD Scientific Advice

Medical devices vigilance versus pharmacovigilance

- The Regulatory System
- Adverse event report - Vigilance
- Post marketing surveillance
- User reporting systems
- Human factors requirements

Device/Drug combination products and companion diagnostics

- The operation of Article 117 and latest guidance

Post Brexit MD and IVD controls in the UK

Future changes, influence of the pharmaceutical package, role of the EMA, regulation of digital devices and global harmonisation

Presenters

Theresa Jeary

Theresa Jeary is Principal Technical Specialist, Medicinal and Biologics, with BSi.

Theresa holds a Master's Degree in Pharmaceutical Science and is eligible to be a Pharmaceutical Qualified Person. She has over 25 years of experience working in both the Pharmaceutical and Medical Device industries and has worked in a variety of roles across the full development cycle from product concept and early stage development, process transfer, validation and regulatory departments, and has been involved in the development of many commercially available medicinal and medical device products.

She has over 10 years of Notified Body experience working at BSi as a technical expert and previously held the position of Head of Notified Body at LRQA. Her area of technical expertise is in device-drug combinations and borderline classifications, and she has completed many successful consultations in this area with many European Competent Authorities and EMA.

Theresa is a frequently invited speaker on medical device legislation and combination products.

David Jefferys

Dr David Jefferys is Senior Vice President for Global Regulatory, Government Relations, Public Affairs and Patient Safety (EMEA, Russia and Australasia) at Eisai. After qualifying, he worked in clinical and academic medicine before spending 20 years as a senior regulator for both medicines and medical devices.

He was executive director of the UK Medicines Control Agency, CEO and Director of the MDA and joint CEO of the MHRA. He was involved in the establishment of the European Medicines Agency, is a CPMP/CHMP member and Chair of the MRFG and PER scheme. For the last ten years he has worked in industry and chairs several key committees for ABPI, EFPIA and IFPMA.

Course dates

3 July 2025	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 14811*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 29 May**
7 November 2025	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 15049*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 03 Oct**

How to book

Online:
ipi.academy/2219

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 presentations were very informative and both Theresa and David had made the course very interesting. They are both very knowledgeable end experienced and delivered an excellent course.

Lenka Elshouly
Procedure Manager | Expert Panels & Groups Office
The European Medicines Agency (EMEA)
Dec 2 2022

★★★★★

Both speakers were excellent and obviously knew their subject in great depth

Peter Davies
Quality Engineer
Bespak Europe Ltd
Nov 23 2017

★★★★★

Enjoyed the course, felt the topics were covered in enough detail given the subject matter. Informal atmosphere with a small number of delegates meant opportunity for questions which were welcomed. Both speakers were clearly passionate about their subject and this was evident during their presentations.

Gillian Hakewill
Regulatory Affairs Officer
SPD Development Company Limited
Nov 23 2017

★★★★★

The course was delivered by highly educated industry experts who shared their extensive knowledge in a clear and entertaining manner. The delegate numbers were small which allowed for a very personal service. I will be recommending Management Forum courses to my colleagues.

Stephanie Kirby
Senior Regulatory Affairs Officer
Bells Healthcare
Nov 23 2017

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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