IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Navigating EU and FDA Regulations for Drug/Device and Device/Drug Combination Products

10-11 September 2025

Gain practical guidance on EU and FDA regulations for drug/device combination products, along with solutions to current challenges, in this comprehensive course.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Understand the regulatory frameworks governing drug/device and device/drug combinations in the European Union and the USA.

The demarcation between medicinal products and devices is becoming ever more important and, with the convergence of emerging novel technologies, the number of drug/device combination products and medical devices incorporating a medicinal substance is increasing. At the same time, cell therapy and tissue-engineered products are being combined with both pharmaceuticals and medical devices. This course will address the European and FDA regulatory requirements, help you define the regulatory route for your product and offer practical guidance on Notified Body expectations, clinical trial considerations and post-market surveillance of borderline products.

Participants will have an invaluable opportunity to discuss the complex issues involved with key regulatory experts in this field.

By the end of the course participants will have the knowledge and skills needed to navigate the complex regulatory landscape for drug/device and device/drug combinations in the EU and the USA effectively. They will be equipped to ensure compliance with the regulatory requirements and facilitate the successful development and commercialisation of these innovative products.

PRE-SEMINAR READING - It is recommended that you have read the **the EU Medical Device Regulation, particularly, Article 120 and the General Safety & Performance Requirements (Annex I) and Technical Documentation (Annexes II and III). For the US, review FDA's Office of Combination Products website** prior to attending this seminar.

Benefits of attending

- **Understand** the European regulatory guidance
- **Know** what your competent authority expects
- **Gain** an insight into notified bodies considerations on drug/device products
- **Learn** how to define the approval route for your product
- **Clarify** the major differences in documentation and approval routes
- **Consider** quality systems requirements for combination products
- **Discover** the FDAs regulatory approach to combination products
- **Hear** how to deal with human tissue engineered products
- **Stay up-to-date** on post market surveillance for combinations products

Who should attend?

Development and regulatory personnel in the medical device, pharmaceutical and diagnostic industries, who need to understand the complex requirements applicable to medical devices incorporating 'pharmaceutical' ingredients, or pharmaceutical products incorporating a device or delivery system.

Programme

Day 1

Introductory overview

- Regulatory agencies in the EU and USA
- Impact of the revision to the MDD
- Transitional period from the MDD to the MDR
- EU regulatory reform proposals
- EMA's viewpoint management
- Evolving regulatory landscape
- Emerging trends

European regulatory guidance: drug/device and device/drug combination products

- European regulatory framework for drug/device and device/drug combinations
- Legal EU definitions of a drug/device and device/drug combination
- Article 117: EU requirements for integral drug/device combinations
- 'In exclusive use with'
- Other combinations – AI systems etc.

European regulatory guidance continued

- Risk management and compliance strategies
- Interactions with regulatory agencies and stakeholders
- Best practices for navigating the regulatory landscape

Defining the regulatory approval pathway for your product

- Product classification
- Differences between device containing ancillary medicinal substances and medicinal products
- Responsibilities of regulatory affairs professionals in product development commercialisation

Medical device CE certification – notified body expectations

- CE marking process for medical devices
- Devices containing ancillary medicinal substances
- Post CE marking expectations and changes
- Notified Body Opinion (NBOp)

MDR's impact on medicinal product directive

- Article 117

Documentation requirements

- Preparing regulatory submissions for drug/device and device/drug combinations
- General Safety and Performance Requirements (GSPR) checklist

Day 2

Clinical trial considerations

- How the regulatory pathway for the final marketed product determines the clinical trial regulation to be followed
- Clinical Trials Directive 2001/20/EC – medicines
- Requirements for clinical development of medical devices
- Clinical data requirements and post-marketing surveillance

Product information

- Labelling requirements under the MDR
- Labelling for combination products
- Electronic Product Information (ePI)

Companion diagnostics

- Regulatory considerations

UK post Brexit

- UK IRP: International Recognition Procedure

Pharmacovigilance for combination products: vigilance or pharmacovigilance

- Understanding the differences between medical device vigilance and pharmacovigilance
- How to handle the challenges posed by combination products
- Pharmacovigilance reporting
- Device vigilance reporting

FDA's approach to combination products

- Background and legal framework
- Definitions of drug, biologics and medical device
- "Borderline" issues and products (v. combination products)
- Types of combination products
- Primary mode of action and FDA's assignment algorithm
- Jurisdiction and designation process

FDA's approach to combination products (continued)

- Submission and regulatory pathways
- Current GMP and quality system requirements
- Post-market safety reporting requirements
- Strategies for development and summary points

Presenters

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.

Tina Amini

Dr. Tina Amini, a pharmacist with PhD in Pharmaceutics. She has over 30 years experience in Pharmaceutical and Medical Devices. She previously held the positions of Head of Notified Body and Senior Technical Specialist at LRQA Notified Body and Pharmaceutical & Medical Device Expert at bsi Notified Body, where she was responsible for Device Drug combination products, Conformity Assessment of a wide range of medical devices and onsite assessments of Quality Management System (QMS) as the lead auditor.

Tina has extensive experience of regulatory expertise for CE marking of medical devices, and has been involved in the classification of borderline products and consultation process with several EU competent authorities and EMA for device/drug products.

Prior to joining Notified Bodies, Tina worked in the Pharmaceutical Industry in a variety of disciplines where she took products through from discovery to commercialisation.

Jonathan Hughes

Jonathan Hughes, Ph.D., FTOPRA, has over 35 years of worldwide regulatory and clinical affairs experience across medical devices, drug / biologic – device combination products and in-vitro diagnostics. He has worked with medical device and pharmaceutical companies, both large and small, across multiple locations to help develop and execute regulatory strategies for market clearance, approval and access.

Jonathan has hands-on experience in a variety of therapeutic areas and has worked across different technologies and types of medical products including medicated devices (devices containing ancillary drug and biologic constituents), drug delivery systems and componentry, sterile and non-sterile disposables and durable equipment, in-vitro diagnostics, software controlled devices and standalone software (including mobile apps). He has experience of regulating medical devices and combination products across most international markets including the European Union, US, Japan, China, Canada and Australia.

Presenters

Andrew Willis

Andrew Willis is an independent consultant providing expert advice and training on global regulatory solutions and pharmaceutical development. Previously, he worked for Catalent Pharma Solutions as VP Regulatory Affairs & Consulting Services, where he was head of a team of internal and external regulatory affairs consultants.

He qualified as a Chemist from the University of Glamorgan, after which he furthered his understanding of pharmaceutical development, working as a research chemist with Parke Davis. He had 10 years manufacturing and analytical experience prior to entering regulatory affairs as a Senior Executive Officer with responsibility for submission of European MAAs and project management of development programs. He has over 30 years' pharmaceutical experience with extensive knowledge in the development and manufacture of sterile, solid oral, inhalation, topical and biotech pharmaceutical products. These experiences have allowed knowledge of many biotech products requirements with experiences of growth hormones and multiple cancer treatments, including development and clinical registration of the first genetically modified live bacterium for such treatment.
He has extensive experience of major European and US regulatory projects, in the clinical and marketing authorisation stages, and has significant experience in coordinating and managing meetings with European and US Health Authorities.

Course date

10-11 September 2025 **Live online**
09:30-17:00 **UK (London)** (UTC+01)
Course code 15211

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 06 Aug

How to book

Online:
ipi.academy/2035

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

★★★★★

It was a very good programme!

Pia Malmberg
Regulatory Affairs Specialist
Mölnlycke Health Care AB
Nov 7 2022

★★★★★

I am satisfied with presentation and content. It was useful to me.

Ines Jurač
Head of Assessment of Quality Department
HALMED (Croatian Agency for Medicinal Products and Medical Devices)
Mar 10 2022

★★★★★

I am satisfied with presentation and content. It was useful to me.

Ines Jurač
Head of Assessment of Quality Department
HALMED (Croatian Agency for Medicinal Products and Medical Devices)
Mar 10 2022

★★★★☆

Very good speakers, very well prepared presentations and contents adequate to the expectations.

Ricado Toribio
Director of Global
Presspart Manufacturing
Nov 7 2022

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