IPI Academy

MANAGEMENT forum



Presented by
Management Forum

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

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

Format:
Bespoke training

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

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-COUSE 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 course.

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.

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

★★★★★

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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:



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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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