IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Development of Combination Products: Critical Interactions

8-9 February 27
+ 15-16 September 27

Linking the technical requirements of device design and pharmaceutical product development.
Using QbD to deliver drug/device combinations.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Drug/device and device/drug combination products are becoming increasingly important in the medical industry. The development and manufacture of these products raises a number of complex issues and the quality and regulatory aspects are challenging.

This interactive course will clarify the EU and US approach to drug/device and device/drug combination products, address the requirements for the device technical file/design file, explain the biological and synthetic drug regulations and look at the registration procedures for these products.

The programme will cover the regulatory strategy to adopt and the relevant aspects of GMP and quality processes, including the data expectations for the CTD. It will also review the key relationships between quality, regulatory, R&D and production. Delegates will find this a comprehensive overview of the requirements for these products and will have an opportunity to discuss the complexities with an expert in this field.

Benefits of attending

- **Clarify** the definitions for drug/device and device/drug combination products in the EU and USA
- **Consider** the requirements for the device technical file/design file
- **Comply** with the biological and synthetic drug regulations
- **Understand** the registration procedures for devices and medicines in the EU and USA
- **Determine** the data required for the Common Technical Document (CTD)
- **Consider** the regulatory strategy depending on your product
- **Gain** practical advice on how to apply the ISO standards

Who should attend

- All development, regulatory and quality personnel involved in the development of combination products (drug/device and device/drug products)
- Pharmacovigilance/vigilance personnel
- Device experts looking to expand their knowledge to medicines and vice-versa

Programme

Day 1

Defining a drug/device and device/drug product

- EU approach
- US approach

Regulatory procedures for drug/device and device/drug products

- EU procedures
- US and Office of Combination Products

Understanding devices

- Medical Device Regulation – EU
- CE marking and Notified Body interactions
- CDRH definitions – US – 510(k) and PMA
- Labelling
- Vigilance requirements

Device technical file/design file

- What is required
- Structure
- Bench testing
- Potential clinical requirements

Workshop: Technical file/design file

Understanding the biological and synthetic drug regulations

- EU/US definition of medicinal product
- Labelling
- Pharmacovigilance
- Quality requirements

Day 2

Registration procedures

- EU approach
- US approach

GMP and ISO standards

- Practical application
- Interpretation of the standards

The CTD

- Where to put data
- Data expectations
- Applying QbD (quality by design)

Workshop: CTD requirements – tracking critical documents

Key considerations for the regulatory strategy

- Deciding which regulatory route to take
- Device and product registrations
- Combination-only registrations
- Desired labelling

Workshop: regulatory strategy

Presenter



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 dates

8-9 February 27	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 16998*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 14 Dec**
15-16 September 27	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 17325*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 21 Jul**

How to book

Online:
ipi.academy/2291

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 **30% 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

★★★★☆

I was hoping to achieve more knowledge about combination product and the regulatory documentations needed for the market authorisation and this was completely accomplished.

Greta Ferrari
Analytical Scientist
Chiesi Farmaceutici
May 5 2022

★★★★★

The speaker was very clear and enabled participants to ask questions with a lot of patience and with clear answers.

Yaniv Menachem
Regulatory Affairs Specialist
Elcam Medical ACA Ltd.
Nov 17 2020

★★★★☆

Overall content of the webinar was very good and covered a lot of topics.. The presentation was clear and included a lot of information. I believe this course was very informative and covered a breath of information in regards to combination product and i gained a lot of useful information and knowledge.

Rebekah Coke
Regulatory Affairs Specialist
Bespak Europe Ltd, Recipharm
Nov 17 2020

★★★★★

The course was very good. The presentations were clear and included a lot of material. The workshops gave an idea how to think outside the box.

Chen Rozilyo
Regulatory Affairs Associate-Experienced
Taro
May 9 2019

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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