Development of Combination Products: Critical Interactions

17-18 Nov 2020, Live webinar
+ 4 more dates - see back page for full schedule

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

Programme at a glance:

- Defining a drug/device and device/drug product
- Regulatory procedures for drug/device and device/drug products
- Understanding devices
- Device technical file/design file
- Workshop: Technical file/design file
- Understanding the biological and synthetic drug regulations
- Registration procedures
- GMP and ISO standards
- The CTD
- Workshop: CTD requirements – tracking critical documents
- Key considerations for the regulatory strategy
- Workshop: regulatory strategy

Full programme inside

NEW FOR 2020: LIVE WEBINAR DATES ADDED

★★★★★ *"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

★★★★ *"The speaker and content was very good. It was clear there was a lot of knowledge and the content was aimed at the right audience"*

Rina Joshi, Associate Director Regulatory Affairs, TEVA

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What this course is about

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 seminar 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

Expert trainer

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.

New for 2020: Live webinars

Amid ongoing uncertainty with travel plans, this is one of our many courses which we are now delivering both in traditional face-to-face format, and as a live webinar.

Delegates attending the webinar format benefit from:

- Reduced prices - and no travel costs
- The same content and presenters
- Interactive virtual classroom environment

Visit our website for more information.

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

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

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Schedule and prices

Three ways to book:

Online
management-forum.co.uk/2291

Email
bookings@management-forum.co.uk

Telephone
+44 (0)20 7749 4730

Ref	Date	Location	Price	Early booking price	Until*
10800	**17-18 Nov 2020**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60		
11037	**5-6 May 2021**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60	GBP **1,099** + VAT = 1,318.80 EUR **1,579** + VAT = 1,894.80 USD **1,786** + VAT = 2,143.20	24 Mar 21
11313	**11-12 May 2021**	Venue TBC	GBP **1,499** + VAT = 1,798.80 EUR **2,099** + VAT = 2,518.80 USD **2,338** + VAT = 2,805.60	GBP **1,299** + VAT = 1,558.80 EUR **1,819** + VAT = 2,182.80 USD **2,026** + VAT = 2,431.20	30 Mar 21
11038	**9-10 Nov 2021**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60	GBP **1,099** + VAT = 1,318.80 EUR **1,579** + VAT = 1,894.80 USD **1,786** + VAT = 2,143.20	28 Sep 21
11430	**11-12 Nov 2021**	Venue TBC	GBP **1,499** + VAT = 1,798.80 EUR **2,099** + VAT = 2,518.80 USD **2,338** + VAT = 2,805.60	GBP **1,299** + VAT = 1,558.80 EUR **1,819** + VAT = 2,182.80 USD **2,026** + VAT = 2,431.20	30 Sep 21

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Multiple booking discounts

Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.

* Note the early booking discount cannot be combined with any other offers or promotional code

The 'Small Print'

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.

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The rest of the 'Small Print', the event cancellation policy and the terms and conditions are on our website, please visit management-forum.co.uk/content/terms-and-conditions