Book before 24 August 2018
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## Development of Drug/Device and Device/Drug Combination Products

To book online go to: **management-forum.co.uk/2291** W

### Dates and venue

6-7 November 2018 **Ref: 10120**
9-10 May 2019 **Ref: 10435**

The Rembrandt Hotel
11 Thurloe Place
London SW7 2RS
Tel: +44 (0)20 7589 8100

### Programme schedule

Registration and refreshments: 09.00
Day 1 09.30 17.00
Day 2 09.00 16.30

### Accommodation


We have arranged a preferential rate for accommodation at the venue. To take advantage of this please state you are a Management Forum delegate. There are limited rooms available at this rate so please book early to avoid disappointment.

**Email: reservations_rembrandt@sarova.co.uk**
**Web: www.sarova-rembrandthotel.com**

For information on alternative accommodation please visit our website:
**management-forum.co.uk/accommodation**

### Three ways to book

**management-forum.co.uk** | **info@management-forum.co.uk** | **+44 (0)20 7749 4730**

### Fees and payment

**EARLY BOOKING DISCOUNT** **Book BEFORE 24 August 2018**
£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2182.80

**FULL PRICE** **Book AFTER 24 August 2018**
£1499.00 + VAT = £1798.80 • €2099.00 + VAT = €2518.80

**Multiple booking discount for 2nd or subsequent delegates - 15%**
£1274.15 + VAT = £1528.98 • €1784.15 + VAT = €2140.98

**Payment options**

1. Invoice which can be paid by bank transfer or credit / debit card
2. Online through our secure website when registering

In-house TRAINING

**Management Forum In-house training**

Coming to Management Forum 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.

To get a **FREE** consultation and to find out how we can work with you call **Aleksandra**, our in-house training expert, on **+44 (0) 20 7749 4730** or email ***inhouse@management-forum.co.uk***

To find out more please visit: ***management-forum.co.uk***

**FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements please advise customer services when booking.**

**PLEASE NOTE: Management Forum Ltd 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 Management Forum will refund the registration fee and disclaim any further liability.**

For event cancellation policy and T&Cs see our website

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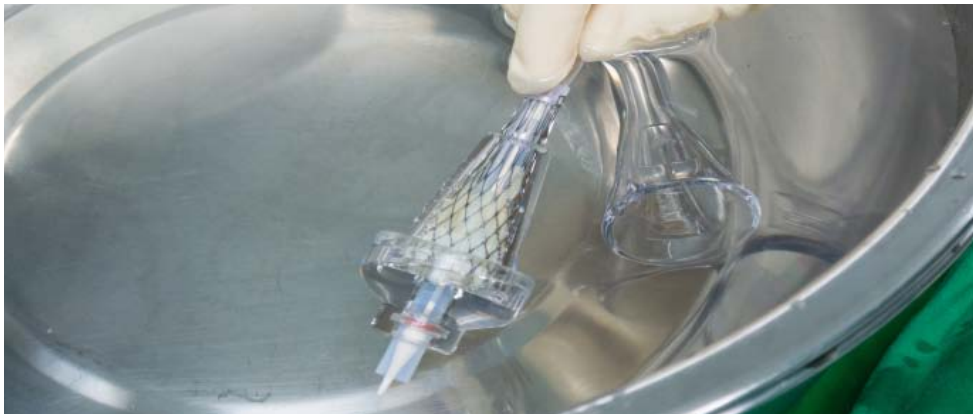
MANAGEMENT forum

# Development of Drug/Device and Device/Drug Combination Products

## A comprehensive overview of the requirements for drug/device and device/drug combination products in the EU and USA

**6-7 November 2018 • 9-10 May 2019 London**



### Benefits in attending:

- **Clarify** the definitions for drug/device and device/drug combination products in the EU and USA
- **Understand** the different regulatory approaches in the EU and USA
- **Consider** the requirements for the Device Technical File/Design File
- **Comply** with the Biological and Synthetic Drug Regulation and its requirements
- **Understand** the registration procedures for devices and medicines in the EU and USA
- **Determine** the data required for the Common Technical Document
- **Consider** the regulatory strategy depending on your product

Expert trainer

**Andrew Willis**
Independent Consultant in Advanced Regulatory Affairs and Pharmaceutical Development, UK

***Includes:*** **Practical workshops**

CPD CERTIFIED The CPD Certification Service

## Introduction

Drug/device and device/drug combination products are becoming increasingly important in the medical industry. The development of these products raises a number of complex issues regarding the development process and their manufacture. The quality and regulatory aspects to consider are also challenging. This seminar will clarify the EU and US approach to drug/device and device/drug combination products. It will discuss the requirements for the Device Technical File/ Design File. The Biological and Synthetic Drug Regulation will be explained as will the registration procedure for these products.

The regulatory strategy to adopt for these products will be considered and the key aspects of GMP and quality processes applicable for drug/device and device/ drug products will also be covered, including the data expectations for the Common Technical Document. Delegates will find this a comprehensive overview of the requirements for these drug/device and device/drug combination products and will have an opportunity to discuss the complexities with an expert in this field.

## Who should attend

All development, regulatory and quality personnel involved in development of combination products (drug/device and device/drug products). Pharmacovigilance/ vigilance personnel will find this seminar beneficial. Also device experts looking to expand their knowledge to medicines and vice-versa.

**You might also be interested in:**

**Drug/Device and Device/Drug Combinations in the EU and USA**
18-19 October 2018, London

To find out more call **Customer Services** on **+44 (0)20 7749 4730** or e-mail ***info@management-forum.co.uk***

## Expert trainer

**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 and he was head of a team of internal and external regulatory affairs consultants.

He has ten 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 28 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.

Andrew has extensive knowledge 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.

**A certificate of attendance for professional development will be available to each participant who completes the course**

## Day one

- **Introduction to course**
- **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
    - 510K 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 regulation**
  - EU/US definition of medicinal product
  - Labelling
  - Pharmacovigilance
  - Quality requirements
- **End of day one**

## Day two

- **Registration procedures**
  - Devices EU/US
  - Medicines EU/US
- **GMP and ISO standards**
  - Practical application
  - Interpretation of the standards
- **Common Technical Document (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**
- **End of seminar**

## In-house training

Elements of this course are also available in-house and can be tailored to your specific needs. Our expert comes to you, saving you time and money. For more information contact **Aleksandra**, our in-house training expert, on **+44 (0) 20 7749 4730** or email ***inhouse@management-forum.co.uk***



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