Book before 9 August 2019 and SAVE £200/€280

Drug/Device and Device/Drug Combinations in the EU and USA

To book online go to: management-forum.co.uk/2035 W

Dates and venue

12-13 September 2019 **Ref: 10508**
2-3 April 2020 **Ref: 10664**

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

Programme schedule

Registration and refreshments: 09.00
Day one: 09.30-17.00
Day two: 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

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Fees and payment

EARLY BOOKING DISCOUNT Book BEFORE 9 August 2019
£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2182.80

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£1499.00 + VAT = £1798.80 • €2099.00 + VAT = €2518.80

Multiple booking discount for 2nd or subsequent delegates - 15%
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Payment options

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

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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

7773

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MANAGEMENT forum

Drug/Device and Device/ Drug Combinations in the EU and USA

Practical guidance on borderline issues and combination products

12-13 September 2019 • 2-3 April 2020 London

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 system requirements for combination products
- **Discover** the FDA's regulatory approach to combination products
- **Hear** how to deal with human tissue-engineered products
- **Stay up to date** on post-market surveillance for combination products

Chair:
Dr David Jefferys, Senior Vice President Global Regulatory, Government Relations and European Product Safety, Eisai Europe Ltd, UK

Expert faculty:
Dr Elizabeth Baker, Group Manager, Licensing Group 1 and Drug/Device Enquiries, MHRA, UK
Dr Tina Amini, Senior Technical Specialist, LRQA Notified Body, UK
Mark Kramer, President, Regulatory Strategies, Inc., USA
Alison Wilson, Principal Consultant, Cell Data Services, UK

CPD CERTIFIED

Drug/Device and Device/Drug Combinations in the EU and USA, London

Introduction

The demarcation between medicinal products and devices is becoming ever more important. In addition, 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 seminar will provide practical advice on the borderline issues concerning these combination products and provide key guidance on the regulatory strategy to follow.

Who should attend?

Development and regulatory personnel in the medical device, pharmaceutical and diagnostic industries who are interested in medical devices incorporating 'pharmaceutical' ingredients, or pharmaceutical products incorporating a device or delivery system.

Pre-seminar reading

It is recommended that you have read the **Medical Device Directive, Essential Requirements Annex 1 and 3** and the relevant sections on combination products in the new **Medical Device Regulation** prior to attending this seminar.

Chair

Dr David Jefferys, Senior Vice President Global Regulatory, Government Relations and European Product Safety, Eisai Europe Ltd, UK

Expert faculty

Dr Elizabeth Baker, Group Manager, Licensing Group 1 and Drug/Device Enquiries, MHRA, UK

Dr Tina Amini, Senior Technical Specialist, LRQA Notified Body, UK

Mark Kramer, President, Regulatory Strategies, Inc., USA

Alison Wilson, Principal Consultant, Cell Data Services, UK

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Day one

09.00 ▶ **Registration and refreshments**

09.30 ▶ **Chair's welcome**
Dr David Jefferys

09.40 ▶ **Introductory overview**
- Background
- Life cycle management
- Exclusivity
- Patents

Dr David Jefferys

10.10 ▶ **European regulatory guidance**
- Life expectations of a competent authority
- Impact of the revision to the MDD
- EMEAs viewpoint management

Dr Elizabeth Baker

11.00 ▶ **Refreshments**

11.20 ▶ **European regulatory guidance (continued)**
Dr Elizabeth Baker

12.30 ▶ **Panel discussion on the EU regulatory requirements**

12.45 ▶ **Lunch**

13.45 ▶ **Defining the regulatory approval route for your product**
- Product classification
- Differences between device containing ancillary medicinal substances and medicinal products

Dr Tina Amini

14.30 ▶ **Medical device CE certification – notified body expectations**
- Devices containing ancillary medicinal substance
- Devices containing ancillary human blood derivative
- Post CE marking expectations and changes

Dr Tina Amini

15.15 ▶ **Discussion session**

15.30 ▶ **Refreshments**

15.45 ▶ **Highlights of major differences in documentation between:**
- Device
- Drug and device
- Device and drug

Dr Tina Amini

16.15 ▶ **Quality and non-clinical considerations for combination products**
- Quality, pre-clinical and biocompatibility issues and how to address these for combination products
- What kind of non-conformance can we expect if you combine a drug and device?

Dr Tina Amini

16.45 ▶ **Discussion session**

17.00 ▶ **End of day one**

Day two

09.00 ▶ **Review of day one**
Dr David Jefferys

09.05 ▶ **Companion diagnostics**
Dr David Jefferys

09.30 ▶ **Clinical trial considerations**
Dr David Jefferys

10.25 ▶ **FDA's approach to combination products**
- Requirements for product assignment, pre-market review and post-market regulation
- Good manufacturing practice (GMP) regulation
- Resources and guidance documents
- Hints and tips on good approaches

Mark Kramer

11.00 ▶ **Discussion session**

11.10 ▶ **Refreshments**

11.20 ▶ **FDA's approach to combination products (continued)**
Mark Kramer

12.45 ▶ **Panel discussion**
Compare and contrast EU and USA regulations

13.15 ▶ **Lunch**

14.15 ▶ **Human tissue-engineered products**
- What are tissue-engineered and advanced therapy combination medicinal products?
- How are these new borderline products regulated in the EU and US?
- What are the practical challenges with development of these products?
- Impact of the proposed regulation on medical devices

Alison Wilson

15.00 ▶ **Discussion session**

15.10 ▶ **Refreshments**

15.30 ▶ **Post-market surveillance for combination products: vigilance or pharmacovigilance?**
Dr David Jefferys

16.15 ▶ **Discussion session**

16.30 ▶ **Close of course**