Book before 21 December 2018 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

14-15 March 2019 **Ref 10411**
19-20 September 2019 **Ref 10508**

The Cavendish Hotel
81 Jermyn Street
London SW1 6JF
Tel: +44 (0)20 7930 2111
(Note: Entrance via Duke Street)

Programme schedule

Registration and refreshments: 09.00
Day one: 09.30-17.00
Day two: 09.00-16.30

Accommodation

When available we have arranged a preferential rate for accommodation at the venue. To take advantage of this price please mention that you are attending the Management Forum seminar when booking your accommodation.

Email: enquiry.cavendish@the-ascott.com
Web: www.thecavendish-london.co.uk

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 21 December 2018
£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2182.80

FULL PRICE Book AFTER 21 December 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

7639

Book Before 21 December 2018 and SAVE £200/€280

MANAGEMENT forum

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

Practical guidance on borderline issues and combination products

14-15 March 2019 • 19-20 September 2019 London

Benefits in 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

Chairman:
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 evermore 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 Devices Directives, Essential Requirements Annex 1 and 3** and the relevant sections on combination products in the new **Medical Device Regulation** prior to attending this seminar.

Chairman

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

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

In-house training

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

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

Day one

09.30 ▶ **Chairman'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**

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**

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**

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**

15.10 ▶ **Refreshments**

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

16.15 ▶ **Discussion**

16.30 ▶ **Close of forum**

© Management Forum Ltd