Drug(Device and Device) in the EU and USA

Benefits of attending:

- Understand the European regulatory guidance
- Know what your competent authority expects
- Gain an insight into the considerations of Notified Bodies 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 for 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 Independent Consultant and previously Senior Technical Specialist, LRQA Notified Body, UK
- Mark Kramer President, Regulatory Strategies, Inc, USA
- Alison Wilson Principal Consultant, Cell Data Services, UK

Fees and payment

<table>
<thead>
<tr>
<th>EARLY BOOKING DISCOUNT</th>
<th>Book BEFORE 24 January 2020</th>
<th>£1299.00 + VAT = £1558.80 • £1819.00 + VAT = £2182.80</th>
</tr>
</thead>
<tbody>
<tr>
<td>FULL PRICE</td>
<td>Book AFTER 24 January 2020</td>
<td>£1499.00 + VAT = £1798.80 • £2099.00 + VAT = £2518.80</td>
</tr>
<tr>
<td>Multiple booking discount for 2nd or subsequent delegates - 15%</td>
<td>£1274.15 + VAT = £1528.98 • £1784.15 + VAT = £2140.98</td>
<td></td>
</tr>
</tbody>
</table>

Payment options

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

Three ways to book

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

EARLY BOOKING DISCOUNT    Book BEFORE 24 January 2020

£1299.00 + VAT = £1558.80 • £1819.00 + VAT = £2182.80

FULL PRICE              Book AFTER 24 January 2020

£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

For event cancellation policy and T&Cs see our website
Why you should attend
The demarcation between medicinal products and devices is becoming ever more important and, 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 address the European and FDA regulatory requirements, help you define the regulatory route for your product and offer practical guidance on notified body expectations, clinical trial considerations and post-market surveillance of borderline products. Participants will have an invaluable opportunity to discuss the complex issues involved with key regulatory experts in this field.

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 for 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 Independent Consultant and previously Senior Technical Specialist, LRQA Notified Body, UK
Mark Kramer President, Regulatory Strategies, Inc, USA
Alison Wilson Principal Consultant, Cell Data Services, UK

‘Excellent delivery, very knowledgeable speakers and a great forum altogether.’
Ana Burman, Team Consulting

‘I am always very selective about which program I sign up for and have high expectations, particularly regarding the relevance of the topic and the qualifications of the speakers. At this training, all my expectations were met, including a good venue and excellent organization!’
Beate Schmidt, Benefits Regulatory Consulting

‘The course was good and the presenters very experienced and knowledgeable.’
Mina Patel, Medtrade Products Ltd

Programme

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
• EMA’s viewpoint management
Dr Elizabeth Baker
11.00  ▶  Refreshments
11.20  ▶  European regulatory guidance (continued)
Dr Elizabeth Baker
12.30  ▶  Panel discussion
• 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
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  ▶  Clinical trial considerations
• How the regulatory pathway for the final marketed product determines the clinical trial regulations to be followed
• Clinical Trials Directive 2001/20/EC – medicines
• Requirements for clinical development of medical devices
• Clinical data requirements and post-marketing surveillance
Dr David Jefferys
10.00  ▶  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  ▶  Refreshments
11.15  ▶  FDA’s approach to combination products (continued)
Mark Kramer
12.45  ▶  Panel discussion
13.00  ▶  Lunch
14.00  ▶  Human tissue-engineered products
• What are tissue-engineered and advanced therapy combination medicinal products?
• What 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
14.45  ▶  Companion diagnostics
• How the regulatory guidance impacts companion diagnostics
• What to consider
Dr David Jefferys
15.15  ▶  Refreshments
15.30  ▶  Post-market surveillance for combination products: vigilance or pharmacovigilance?
• Understanding the differences between medical device vigilance and pharmacovigilance
• How to handle the challenges posed by combination products
• Pharmacovigilance reporting
• Device vigilance reporting
Dr David Jefferys
16.15  ▶  Discussion session
16.30  ▶  Close of course