Book before 9 March 2018 and SAVE £100 / €140

Save £100 / €140 if both courses booked

To book online: **management-forum/pharmaceutical** W

Dates and venue

An Essential Overview of the Medical Device Industry

11 May 2018 **Ref: 10199**
8 November 2018 **Ref: 10237**

An Essential Overview of the Pharmaceutical Industry

4 May 2018 **Ref: 10169**
9 November 2018 **Ref: 10170**

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

Programme schedule for each course

Registration and refreshments: 09.00
Start of course: 09.30
Close of course: 17.00

Accommodation

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

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

Three ways to book

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

Fees and payment

EARLY BOOKING DISCOUNT Book BEFORE 9 March 2018
£599.00 + VAT = £718.80 • €839.00 + VAT = €1006.80

FULL PRICE Book AFTER 9 March 2018
£699.00 + VAT = £838.80 • €979.00 + VAT = €1174.80

Multiple booking discount for 2nd or subsequent delegates - 15%
£594.15 + VAT = £712.98 • €832.15 + VAT = €998.58

Payment options

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

Book both courses

SAVE £100/€140 off Essential Overview of Pharmarceutifcal Industry when registering for both events. To register visit our website management-forum.co.uk or call customer services on +44 (0)20 7749 4730

In-house training

These courses 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**

The small print

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.

HOW TO REGISTER AND PAY: A VAT invoice and booking confirmation will be sent within 7 days, please contact us if you have not heard anything after that time. Payment can be made by credit/debit card, by bank transfer (for bank account details please see payment details section on our website). VAT no GB 341232109. Any questions please contact Customer Services on +44 (0)20 7749 4730. **ALL PAYMENTS MUST BE RECEIVED IN ADVANCE OF THE EVENT.**

MULTIPLE BOOKING DISCOUNTS: This discount may not be used in conjunction with any other offer

CANCELLATIONS AND TRANSFER: Once we have received your booking the place(s) are confirmed.

Delegate	Up to 28 days before course	27 to 14 days before course	13 to 0 days before course
Cancellation	10% admin fee	100% admin fee	100% admin fee
Transfers	Free	10% admin fee	100% admin fee
Substitution	Free	Free	Free

A maximum of one transfer is allowed. After the transfer no cancellation can be accepted and the full invoiced fee will be charged. Transfers are subject to payment of the difference on higher value courses. All cancellations must be received in written form.

For event cancellation policy and T&Cs see our website

Book Before 9 March 2018 and SAVE £100 / €140

Includes: Interactive workshop sessions

MANAGEMENT forum

An Essential Overview of the Medical Device Industry

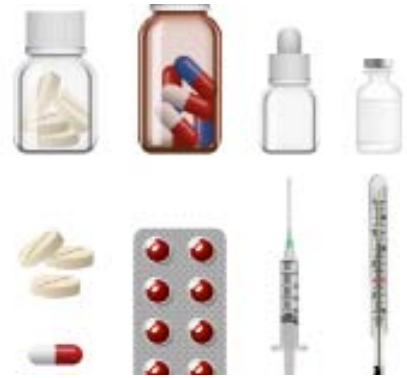
Topics to be covered include:

- Gain an overview of the medical device industry and clarify the differences in approach from pharmaceuticals
- Learn about medical device CE marking
- Gain an overview of medical device and IVD regulation and the new Medical Device Regulation
- Understand clinical trial controls and device vigilance
- Discuss device/drug combination products
- Understand the differences from the pharma industry

11 May 2018
8 November 2018
LONDON

Expert trainers:
David Jefferys, Senior Vice President, Eisai Ltd
Theresa Jeary, Technical Manager, LRQA

An Essential Overview of the Pharmaceutical Industry



Benefits of attending this seminar:

- Increase your understanding of the pharma industry
- Develop your knowledge of the stages of drug development from drug discovery through to marketing
- Get-to-grips with the phases of clinical trials, regulatory processes and pharmacovigilance requirements
- Understand the roles and responsibilities of key departments and how they work together
- Demystify the technical terminology and jargon

4 May 2018
9 November 2018
LONDON

Expert trainer:
Dr Laura Brown
Course Director, School of Pharmacy, University of Cardiff and Independent Pharmaceutical Training Consultant

CPD CERTIFIED The CPD Certification Service

An Essential Overview of the Medical Device Industry

11 May 2018 • 8 November 2018, London

Why should you attend?

The pharmaceutical industry is increasingly developing device combination products and looking to use novel methods of drug delivery to enhance the performance of medicine and as a part of life cycle management. Medical devices are also being employed to monitor compliance in clinical trials and post marketing as well as being used to monitor patients in trials. This one-day workshop aims to give all the key information necessary to understand the regulation of medical devices and diagnostics and to appreciate the key differences from pharmaceutical regulation.

Who should attend?

The course has been specifically designed to meet the needs of those working in pharmaceuticals and in allied business functions who need to understand the medical device sector. The course will be particularly relevant for regulatory staff, those in clinical research, medical affairs and business development.

Expert trainers

David Jefferys is currently Senior Vice President with Eisai responsible for Global Regulatory, Government Relations, Public Affairs and Patient Safety (EMEA, Russia and Australasia). After qualifying in medicine he worked in clinical and academic medicine, before spending 20 years as a senior regulator for both medicines and medical devices.

Theresa Jeary is the Technical Manager for medical devices at LRQA responsible for devices drug products and Class III Medical Conformity Assessment. She has 25+ years' experience working in both the pharmaceutical and medical device industries and has worked in a variety of roles across the full development cycle She has conducted many successful consultations with many of the European Competent Authorities as well as the European Medicines Agency (EMA) borderline products.

Programme

- What is a medical device?
- What are the key differences in approach from pharmaceuticals
- How is the device market developing
- An overview of the medical device and in-vitro diagnostics legislation, including the implementation of the 2017 Medical Device and IVD Regulations
- The role of the Competent Authority and Authorised Representative
- Brexit an update – what might happen
- What is a Notified Body and how are medical devices and IVDs evaluated
- What are the data requirements?
- How to work with a Notified Body
- Clinical trial controls for devices
- Device vigilance *vs* pharmacovigilance
- Device/drug combination products and companion diagnostics
- Building a global approval strategy on an EU CE Mark Approval

An Essential Overview of the Pharmaceutical Industry

4 May 2018 • 9 November 2018, London

Why should you attend?

This programme will give you an invaluable overview, refresher and update of the pharmaceutical Industry, from discovery of the molecule through development to marketing. It will provide a step-by-step understanding of the main areas of drug development and will discuss the roles and responsibilities of key staff involved. You will be given a comprehensive glossary of the most commonly used industry terms which will be an invaluable reference to help you get-to-grips with the technical terminology and jargon.

Who should attend?

All those wanting to achieve a better understanding of how the pharmaceutical industry works. The course will be particularly helpful for those wanting to understand what other departments do, for new staff working in the industry and for non-scientific and administrative personnel.

Expert trainer

Dr Laura Brown is an independent QA and Training Consultant and Director of the MSc in Clinical Research, School of Pharmacy at the University of Cardiff and Course Director of the MSc Regulatory Affairs, TOPRA. Laura has many years' experience in the pharmaceutical industry. She has worked for several companies including Glaxo Wellcome, Hoechst Marion Roussel, Good Clinical Research Practices and Phoenix International. She has worked as a Clinical Research Manager, Audit Director and as Head of a Training Department.

Book both courses and SAVE £100/€140 off *Essential Overview of the Pharmaceutical Industry* when registering for both events. Visit our website management-forum.co.uk or call +44 (0)20 7749 4730 to book

A certificate of attendance for professional development will be available to each participant

Programme

- **How are drugs developed?**
  - Overview of drug development and why we patent drugs
  - The difference between a biotechnology company and a pharmaceutical company
  - Drug discovery - how to identify New Chemical Entities (NCE)
  - Non-clinical/pre-clinical development of lead compounds - the importance of examining safety
- **Demystifying the jargon and terminology**
- **What are the roles and responsibilities of the people in the pharmaceutical industry?**
- **Clinical trials and how they advance a drug to market**
  - Gaining a clear picture of what happens at each phase of clinical research: - Phase I - Phase IV
  - Ensuring the quality of the data: monitoring, auditing and working to ICH
- **Data management and statistics**
- **Pharmacovigilance**
  - What is pharmacovigilance?
  - Overview of safety reporting, signal detection, evaluation and risk management
- **Regulatory processes**
  - Overview of regulatory submission and approval procedures
  - Understanding the ICH process
  - The electronic Common Technical Document (eCTD), and the impact of the EU Clinical Trial Regulation
- **Potential impact of Brexit on the pharma Industry**
- **How are drugs marketed and sold**