Book before 4 October 2019 and SAVE £200/€280

An Introduction to the Design and Development of Medical Devices

To book online go to: management-forum.co.uk/2047 W

Dates and venue

28-29 November 2019 **Ref: 10591**
27-28 May 2020 **Ref: 10627**

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: 09.00-16.45

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 4 October 2019
£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2182.80

FULL PRICE Book AFTER 4 October 2019
£1499.00 + VAT = £1798.80 • €2099.00 + VAT = €2518.80

Multiple booking discount for 2nd or subsequent delegates - 15%
£1274.15 + VAT = £1534.98 • €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, 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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NEW COURSE

MANAGEMENT forum

An Introduction to the Design and Development of Medical Devices

Including device constituent parts of combination products

28-29 November 2019 • 27-28 May 2020 London

Benefits of attending:

- **Gain** a comprehensive overview of the design and development process
- **Comply** with the regulatory requirements and standards
- **Learn** about design controls
- **Review** materials and biocompatibility
- **Access** key information on documentation management and systems
- **Understand** how risk should be managed
- **Consider** human factors and usability studies

Expert trainer:

David Howlett, Director, PharmaDelivery Solutions Ltd

Includes: Interactive workshop sessions

An Introduction to the Design and Development of Medical Devices, 28-29 November 2019 • 27-28 May 2020, London

Why you should attend

This course introduces those who are new to medical device design and development to the critical elements of the process. It aims to provide delegates with an introductory insight into the tools and techniques required to design and develop a medical device. The importance of safety and efficacy will be covered, as will risk management and documentation. As combination products are a huge market, the course will also address device constituent parts of combination products.

Attending this training will provide delegates with a comprehensive appraisal of the critical elements and processes, and provide an opportunity to discuss the complexities involved with an experienced industry expert.

Who should attend?

- Design and development personnel
- Development engineers
- Quality personnel
- Regulatory personnel
- Design control professionals
- Documentation managers
- Programme managers
- Anyone who needs an overview of the medical device design and development process

In-house TRAINING

Management Forum in-house training

This course is also available in-house and can be tailored to your specific needs. Our experts come to you, saving you time and money. 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***

For more information, please visit: ***management-forum.co.uk***

Expert trainer

David Howlett, Director, PharmaDelivery Solutions Ltd, provides specialised consultancy service in the field of drug delivery combination products and associated medical device development. This has led to involvement in projects with a focus on pulmonary, topical, parenteral, nasal and other delivery routes, with an international client base. Much of the activity of PharmaDelivery Solutions Ltd is focused in the area of design and development programme support, regulatory GAP analysis and generation of documentation associated with design control and design verification. David has over 35 years' experience in the design, development, industrialisation and approval of inhalation drug delivery systems, combination products and medical devices.

He has previously been an Honorary Teaching Fellow in the School of Pharmacy and Pharmaceutical Sciences at the University of Manchester and is author/tutor for the Pharmaceutical Industry Advanced Training (PIAT) MSc module on Inhalation Dosage Forms. In addition, he has presented numerous lectures relating to the design, development, industrialisation, commercialisation and regulation of combination products.

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

Programme

Day one

09.00 ▶ **Registration and refreshments**

09.30 ▶ **Welcome and introduction**

09.45 ▶ **Overview to the regulations and market routes**
- Regulatory pathways
- Medical Device Directive (MDD) vs Medical Device Regulation (MDR) – key differences
- EU vs US (FDA) – markets to consider

11.00 ▶ **Refreshments**

11.20 ▶ **Overview to the regulations and market routes (continued)**
- Medical device vs combination product (drug/device and device/drug) – which regulation applies?
- Device classification and the implications for your product
- Resources and sources

12.30 ▶ **Lunch**

13.30 ▶ **The design and development process**
- The stages of design and development
- Key considerations
- Terminology
- Intended use
- Project complexity
- Mandatory requirements
- Design and development tools

15.00 ▶ **Workshop one**

15.30 ▶ **Refreshments**

15.50 ▶ **The design and development process (continued)**
- Inspiration, innovation and determination
- Materials and biocompatibility
- DFx, Design for……?
- Manufacturing – key considerations

17.00 ▶ **End of day one**

Day two

09.00 ▶ **Design control**
- Appropriate design and development planning
- Translation of marketing requirements
- SMART design inputs
- Is a trace matrix appropriate?
- Meaningful design outputs

10.40 ▶ **Refreshments**

11.00 ▶ **Design control (continued)**
- Verification and validation
- Design reviews
- Design transfer
- Design history file vs technical file
- Change control
- Notified Bodies (NB)

12.30 ▶ **Lunch**

13.30 ▶ **Risk management – what is required?**
- What is risk management and when should it be applied?
- What does the guidance say?
- Help or hindrance?
- How to implement a practical risk management plan
- Tools and techniques to help you succeed

14.30 ▶ **Workshop two**

15.00 ▶ **Refreshments**

15.20 ▶ **Clinical evaluation, human factors and usability – how to comply**
- Planning your clinical evaluation
- How to incorporate human factors and usability studies into your design and development process – MDR and FDA requirements
- User instructions
- Training considerations – when and who do you need to train?
- Formative studies
- Validation/summative studies

16.30 ▶ **Discussion session and Q & A**

16.45 ▶ **Close of course**

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