Book before 6 April 2018
and SAVE £300 / €420

An Introduction to the Medical Device Regulation

To book online go to: **management-forum.co.uk/1990** W

Dates and venue

14-16 May 2018 **Ref: 10097**
12-14 November 2018 **Ref: 10098**

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	Day two	Day three
Start	09.30	09.00	09.00
Close	17.15	17.00	16.00

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.
http://www.thecavendish-london.co.uk/
info@thecavendishlondon.com

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 6 April 2018**
£1549.00 + VAT = £1858.80 • €2169.00 + VAT = €2602.80	
FULL PRICE	**Book AFTER 6 April 2018**
£1849.00 + VAT = £2218.80 • €2589.00 + VAT = €3106.80	
Multiple booking discount for 2nd or subsequent delegates - 15%	
£1571.65 + VAT = £1885.98 • €2200.65 + VAT = €2640.78	

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

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**

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 6 April 2018 and SAVE £300 / €420

A repeat of this comprehensive course - now extended to three days due to demand!

MANAGEMENT forum

An Introduction to the Medical Device Regulation

Gain a comprehensive understanding of the regulatory requirements

14-16 May 2018 • 12-14 November 2018 London

Benefits of attending this seminar:

- **Understand** the new Medical Device Regulation (MDR)
- **Learn** the role of a Notified Body
- **Know** what a Competent Authority expects
- **Hear** more on classification
- **Better understand** Conformity Assessment Procedures
- **Comply** with manufacturing responsibilities
- **Discover** medical device vigilance
- **Plan** your clinical evaluations
- **Discuss** Drug/Device combinations

Expert trainers:

Janette Benaddi, Independent Medical Device Consultant and Trainer, UK
Will Burton, Director, Russell Square Quality Representatives Ltd
Theresa Jeary, Head of Notified Body, Medical Devices, LRQA Notified Body

CPD CERTIFIED The CPD Certification Service

Includes: **Interactive discussion sessions**

An Introduction to the Medical Device Regulation 14-16 May 2018 • 12-14 November 2018, London

Benefits of attending

This seminar provides a detailed introduction to the European medical device legislation. It will explain the new regulations and which products are covered, the invovement of Notified Bodies, how to choose one and outline what a manufacturer must do. It will also cover the documentation necessary to apply for the CE Mark.

This is an excellent introduction from leading experts in the field and delegates should expect three comprehensive days of training.

Who should attend

Past delegates include personnel from the following departments: regulatory affairs, pharmacovigilance, quality assurance and technical support.

This seminar will be of interest to all personnel who are new to the medical device industry, all those who intend to place a medical device on the market and anyone who requires an overview of the medical device sector.

Course leader

Janette Benaddi, Independent Medical Device Consultant and Trainer. She is a seasoned medical device expert with over twenty years' experience in the medical device sector. She has worked with several multinational organisations in various clinical, regulatory and marketing roles. She has extensive experience of conducting clinical studies with medical device products as well as regulatory expertise for CE marking of devices. Janette sits on several committees in the device community and industry and has been an instrumental advocate of improving and advancing medical device research in the UK. She has published several articles relating to medical device regulation and clinical studies.

Expert trainers

Will Burton, Director of Russell Square Quality Representatives Ltd

Theresa Jeary, Head of Notified Body, Medical Devices, LRQA Notified Body

Programme

Day one Tutor: Janette Benaddi

09.30 ▶ Welcome and introduction

09.45 ▶ What is a medical device?
- Definition
- Examples

10.45 ▶ Discussion

11.00 ▶ Refreshments

11.15 ▶ Europe and the Medical Device Regulation - overview of the regulations applicable for bringing a medical device to market

12.15 ▶ Discussion

12.30 ▶ Lunch

13.30 ▶ What is a Competent Authority, Notified Body and an Authorised Representative?
- How do they inter-relate?
- Responsibilities of each party

14.30 ▶ Classification of devices
- What are the classes and how do we classify devices

15.15 ▶ Discussion

15.30 ▶ Refreshments

15.45 ▶ Conformity Assessment Procedures
- The routes to CE marking
- What is required for each class of device

16.30 ▶ Workshop 1: Classification

16.45 ▶ Discussion

17.15 ▶ End of day one

Day two Tutors: Will Burton and Janette Benaddi

09.00 ▶ Manufacturer's responsibilities
- Technical file and design dossier requirements

10.00 ▶ Quality systems
- EN ISO 13485: 2012 and 2016
- The requirements for a quality system

10.45 ▶ Discussion

11.00 ▶ Refreshments

11.15 ▶ Labelling of devices
- Use of language and symbols
- Instructions for use

12.15 ▶ Discussion

12.30 ▶ Lunch

13.30 ▶ Workshop 2: Labelling

14.15 ▶ Discussion

14.30 ▶ Clinical evaluations
- European regulatory environment
- When are clinical investigations necessary
- What is required by the Competent Authority, Ethics Committee and Notified Body

15.30 ▶ Discussion

15.45 ▶ Refreshments

16.00 ▶ Workshop 3: Clinical evaluations

16.45 ▶ Discussion

17.00 ▶ End of day two

Day three Tutors: Janette Benaddi and Theresa Jeary

09.00 ▶ Medical device vigilance
- Adverse event reporting
- Reporting requirements
- Post Market Surveillance (PMS)

10.00 ▶ Workshop 4: Vigilance

10.45 ▶ Discussion

11.00 ▶ Refreshments

11.15 ▶ Drug/Device combinations
- Drug or device?
- Examples of classification

12.15 ▶ Discussion

12.30 ▶ Lunch

13.30 ▶ Devices incorporating material of animal origin
- Animal derived materials legislation
- Directive 2003/32/EC

14.30 ▶ Discussion

14.45 ▶ Refreshments

15.00 ▶ The revision to the regulations for medical devices

15.45 ▶ Question and answer session

16.00 ▶ End of seminar

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

Documentation

Participants will receive a course material folder containing comprehensive documentation provided by the speakers, which will be a valuable source of reference for the future.

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