

An Introduction to the Medical Device Regulation

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Dates and venue

20-22 November 17
14-16 May 2018

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

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

We have arranged a preferential rate for accommodation at the venue. To take advantage of this please contact reservations_rembbrandt@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



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Fees and payment

EARLY BOOKING DISCOUNT Book BEFORE 8 September 2017

£1549.00 + VAT = £1858.80 • €2169.00 + VAT = €2602.80

FULL PRICE Book AFTER 8 September 2017

£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.

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

An Introduction to the Medical Device Regulation

Gain a comprehensive understanding of the regulatory requirements

20-22 November 2017 • 14-16 May 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

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 involvement 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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from this training then we can come to you. We bring our experts to you and can develop the programme to your team's specific needs at a fraction of the cost of multiple public course fees. To find out how we can work with you, what you will get and for how much, please call **Customer Services** on **+44 (0)20 7729 4730** or email **inhouse@management-forum.co.uk**

