Book Before 21 December 2018 and SAVE £200/€280

MANAGEMENT forum

New Medical Device Regulation

Managing the transition to the new regulation including an update on Brexit

6-7 March 2019 • 24-25 September 2019 London

Benefits of attending:

- **Hear** from key opinion leaders regarding the impact of the changes
- **Get** an essential understanding of the new regulation
- **Be aware** of how the changes will be implemented by Member States and Notified Bodies
- **Plan** how to manage the transition successfully
- **Understand** how to comply with the new regulations
- **Discuss** the implications of Brexit

Expert faculty

Chairman:

Dr David Jefferys, Senior Vice President Global Regulatory, Government Relations and European Product Safety, Eisai Europe Ltd, UK

Speakers:

Oliver Bisazza, Head of Regulatory Affairs, MedTech Europe (European trade association), Belgium
Theresa Jeary, Head of Notified Body, Medical Devices, LRQA, UK
Janette Benaddi, Independent Medical Device Consultant, UK

CPD CERTIFIED The CPD Certification Service

New Medical Device Regulation

6-7 March 2019 • 24-25 September 2019, London

Introduction

During a period of great uncertainty and opportunity within the medical technology and diagnostics sectors, this seminar will help you prepare for these changes and operate successfully in Europe. The seminar will provide in-depth coverage of new regulations and how they will be implemented by Member States and Notified Bodies. You will hear the latest thoughts on clinical development, safety monitoring and the implications of Brexit.

This is a seminar you cannot afford to miss as you put in place your strategies for the new environment.

Who should attend?

Personnel from the following departments: regulatory affairs, clinical studies, vigilance, PMS, quality systems, technical support and business development.

This seminar will provide key guidance and interpretation of the changes to the regulation and will be of value to all those who are involved with placing a medical device on the market, and anyone who requires an essential overview of the new medical device regulation and its impact on the industry and working practices.

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

Group discounts available upon request

For more information, please contact our Customer Services department on Tel: +44 (0)20 7749 4730 or email: info@management-forum.co.uk

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Management Forum in-house training

Empower your whole team with elements of this training as an in-house programme.
If you have five or more participants who could benefit from this training then we can come to you. We can develop the programme to your team's specific needs at a fraction of the cost of multiple public course fees.

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***

Dates and venue

6-7 March 2019
24-25 September 2019

The Rembrandt Hotel
11 Thurloe Place
London SW7 2RS

Tel: +44 (0)20 7589 8100

The Rembrandt Hotel is located opposite London's Victoria and Albert Museum (V&A), and is a ten-minute walk to the Natural History Museum, Science Museum, Hyde Park, Harrods and the Royal Albert Hall.

A superb location surrounded by restaurants, bars, shops and cultural attractions.

Programme

Day one

09.30 **Chairman's welcome and introduction**
Dr David Jefferys

09.45 **Introduction and background to the new regulation**
- Medical Device Co-ordination Groups

Dr David Jefferys

10.45 **Discussion**

11.00 **Refreshments**

11.30 **Key preparation for successful implementation**
- Where, what, how?
- A road map for the new regulation
- EUDAMED database - maximising the potential
- Implications of Brexit

Oliver Bisazza

12.30 **Discussion**

12.45 **Lunch**

13.45 **Notified Bodies: how the changes will impact NBs and manufacturers - including the new rules for IVD conformity assessment**
- Accreditation and designation of NBs
- How to register with NBs
- Conformity assessment applications

Theresa Jeary

15.00 **Discussion**

15.10 **Refreshments**

15.30 **Clinical investigations - what is required?**
- Greater protection for patients participating in clinical investigations
- Products to have an acceptable benefit to risk ratio
- Product safety and performance
- Changes in data requirements
- Restrictions by individual member states

Janette Benaddi

16.45 **Discussion**

17.00 **Close of day one**

Day two

09.00 **Welcome to day two**
Dr David Jefferys

09.30 **Increased vigilance and post-market surveillance - how to comply**
- Post-market surveillance systems appropriate for your device and risk classification
- Periodic Safety Update Reports (PSURs)
- Manufacturers' response times to serious public health threats and deaths caused by devices

Dr David Jefferys

10.30 **Discussion**

10.45 **Refreshments**

11.15 **IVDs and companion diagnostics**
- Implications and timelines
- New IVD conformity assessment rules

Theresa Jeary

12.30 **Discussion**

12.45 **Lunch**

13.45 **Other essential considerations**
- Authorised representatives - increased responsibilities and requirements
- Single registration numbers for all economic operators
- New categories
- Single-use devices - reprocessing?

Dr David Jefferys

14.45 **Discussion**

14.50 **Refreshments**

15.15 **Other essential considerations (continued)**
- Unique device identification
- Safety and clinical performance summaries
- Strategies to address the new requirements

Dr David Jefferys

16.15 **Panel discussion and key take-home messages**

16.30 **Close of course**

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To book online go to: **management-forum.co.uk/2236** **W**

Dates and venue

6-7 March 2019	**Ref: 10410**
24-25 September 2019	**Ref: 10503**

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Programme schedule

Registration and refreshments:	09.00
Day one:	09.30 - 17.00
Day two:	09.00 - 16.30

Accommodation

We have arranged a preferential rate for accommodation at the venue. To take advantage of this please contact the hotel on the email below and 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 21 December 2018**
£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2182.80

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£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

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.

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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