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MANAGEMENT forum

# New Medical Device Regulation

## Managing the transition to the new regulation
## Including an update on Brexit

**26-27 February 2018 • 25-26 September 2018 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

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

**Expert faculty:**
**Graeme Tunbridge,** Head of Medical Devices EU Policy, Medicines and Healthcare Products Regulatory Agency (MHRA), UK
**Theresa Jeary,** Head of Notified Body, Medical Devices, LRQA, UK
**Janette Benaddi,** Independent Medical Device Consultant, UK

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# New Medical Device Regulation

**26-27 February 2018 • 25-26 September 2018, London**

## Introduction

This is a period of great change, uncertainty and opportunity within the medical technology and diagnostics sectors. This seminar will help you prepare for these changes and operate successfully in the changed environment in Europe. The seminar will cover in depth the 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**

## Expert faculty

### Chairman:

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

### Speakers:

**Graeme Tunbridge**
Head of Medical Device EU Policy, Medicines and Healthcare products Regulatory Agency (MHRA)

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

**Janette Benaddi**
Independent Medical Device Consultant, UK

In-house TRAINING

**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 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 7749 4730 or email: ***info@management-forum.co.uk***

## Dates and venue

26-27 February 2018
25-26 September 2018

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 10-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

**Graeme Tunbridge**

**12.30** **Discussion**

**12.45** **Lunch**

**13.45** **Notified Bodies: How the changes will impact NBs and manufacturer's - 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** **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)
- Manufacturer's response times to serious public health threats and deaths caused by devices

**Dr David Jefferys**

**16.45** **Discussion**

**17.00** **Close of day one**

## Day two

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

**09.30** **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**

**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 forum**

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# New Medical Device Regulation

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

## Dates and venue

26-27 February 2018 **Ref: 10047**
25-26 September 2018 **Ref: 10048**

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

## Programme schedule

| | |
|---|---|
| Registration and refreshments: | 09.00 |
| Start of course: | 09.30 |
| Close of course: | 16.30 |

## 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 22 December 2017**
**£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2182.80**

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£1499.00 + VAT = £1798.80 • €2099.00 + VAT = €2518.80

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### 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 our **Customer Services** Department 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**