MANAGEMENT forum

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New Regulations for Medical Devices and IVDs in Europe

30 Jun-1 Jul 2022, Live webinar
+ 1 more date - see back page for full schedule

During a period of change and opportunity within the medical technology and diagnostics sectors, this seminar will help you prepare and operate successfully in Europe and the UK post Brexit.

Programme at a glance:

- Introduction and background to the new regulations – MDR and IVDR
- What has changed from the MDD?
- Notified Bodies: how the changes will impact NBs and manufacturers – including the new rules for IVD conformity assessment
- Regulation of Medical Devices and IVDs in the UK
- IVDs and companion diagnostics
- Clinical evidence
- Combination products
- Increased vigilance and post market surveillance
- Other essential considerations from the new legislation and future changes

Full programme inside

★★★★ *"The speakers were very professional and knowledgeable. They delivered the content in an easy format and allowed plenty of time for questions and interaction from the attendees. I particularly liked the section regarding the context of the regulation and background to its development which will help me when explaining this to my clients."*

Stephen Rowe, Managing Director, SGR Consulting Services Ltd

★★★★★ *"Very well run, met my objectives, and speakers were interesting, approachable and very knowledgeable."*

Lucie Green, QA Manager, Vyaire Medical Products

★★★★ *"A relaxed, open forum where you felt comfortable to ask any questions you needed through the presentations and the day. The speakers were all very clear, concise, factual and interactive."*

Holly Widnall, Project Manager, Bedfont Scientific Ltd

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Course overview

During a period of change and opportunity within the medical technology and diagnostics sectors, this seminar will help you prepare and operate successfully in Europe and the UK post Brexit. The programme will provide in-depth coverage of the new regulations and how they will be implemented by member states, the UK and Notified Bodies. You will hear the latest thoughts on clinical development, safety monitoring, the role of authorised representatives, economic operators, and the implications of Brexit.

There will be plenty of opportunities to discuss the implications of the changes with our expert faculty, and you will gain valuable guidance on successful implementation of the regulatory changes for your company products.

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

Key points to be covered:

- What have we learnt from the first 9 months of the operating under the new EU Medical Devices Regulation?
- Answers to the open questions on Eudamed , EU Vigilance procedures & Combination products
- How is the MDCG operating?
- The experience of Notified Bodies under the new Regulation
- How will the new clinical trial system evolve?
- Complying with the new clinical data requirements
- Discussion on the new controls on software in medical devices, and approaches to controlling digital medicine
- Are you prepared for the introduction of the EU IVD Regulation in May 2023 – Including:
  - Companion diagnostics
  - Role of the EMA and CHMP
  - Pre-qualification and validation of diagnostics
  - Genetic testing

Who should attend

- Regulatory affairs
- Clinical studies
- Vigilance
- PMS
- Quality systems
- Technical support and business development.

Why you should attend

The seminar will provide key guidance and interpretation of the changes to the regulations and will be of value to all those who are involved with placing a medical device on the market in Europe and the UK post Brexit, and anyone who requires an essential overview of the new MDR, IVDR and its impact on the industry and working practices.

★★★★ *"Management Forum have become my go-to provider of life science training. They always find excellent speakers who present their subject matter in a very knowledgeable, complete and thoroughly enjoyable way. I have always found Management Forum courses to be excellent value for money and the New Medical Device Regulation course was no exception."*

Stephen Matthews, Validation Consultant, Smart Process Solutions Ltd.

★★★★★ *"Excellent training performed by very knowledgeable speakers."*

Marie-Pierre Hontas, Senior Director Scientific & Clinical Affairs, Vexim SA – Stryker IVS

★★★★★ *"Good, complete coverage of the new regulations. Good anticipating on discussed items."*

Marcel Steenhof, Toxicologist and Regulatory Affairs Profesisonal, Keystone Europe BV

Expert trainers

David Jefferys

Dr David Jefferys is Senior Vice President for Global Regulatory, Government Relations, Public Affairs and Patient Safety (EMEA, Russia and Australasia) at Eisai. After qualifying, he worked in clinical and academic medicine before spending 20 years as a senior regulator for both medicines and medical devices.

He was executive director of the UK Medicines Control Agency, CEO and Director of the MDA and joint CEO of the MHRA. He was involved in the establishment of the European Medicines Agency, is a CPMP/CHMP member and Chair of the MRFG and PER scheme. For the last ten years he has worked in industry and chairs several key committees for ABPI,EFPIA and IFPMA.

Theresa Jeary

Theresa Jeary holds a Master's Degree in Pharmaceutical Science and is eligible to be a Pharmaceutical Qualified Person. Theresa has over 25 years' experience working in both the Pharmaceutical and Medical Device industries and has worked in a variety of roles across the full development cycle from product concept and early stage development, process transfer, validation and regulatory departments, and has been involved in the development of many commercially available medicinal and medical device products.

She has over 10 years Notified Body experience working at BSi as a technical expert and until January held the position of Head of Notified Body at LRQA. Her area of technical expertise is in device-drug combinations and borderline classifications, and she has completed many successful consultations in this area with many European Competent Authorities and EMA.

Theresa now works as a consultant to the Pharmaceutical and Medical device sectors and is a frequently invited speaker on medical device legislation and combination products.

Janette Benaddi

Janette Benaddi is a business mentor, international speaker/trainer and consultant to the medical device industry. Janette has over 25 years' experience of managing pre and post market clinical studies in both devices and pharmaceuticals. Janette has worked with several multinational organizations 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. Specifically she has been involved in writing and reviewing hundreds of Clinical evaluation reports for the medical device industry, she has also provided training to Notified bodies in this subject.

Janette qualified as a registered nurse in 1984, she has a BSc in Management studies, a Diploma in Company Direction, and a Diploma in Management studies, holds a teaching certificate and is a Chartered Scientist and Chartered Director. 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. Janette has published several articles relating to medical device regulation and clinical studies.

Introduction and background to the new regulations – MDR and IVDR

- New features
- Key roles
- Key learnings

What has changed from the MDD?

- What have we learnt so far?
- What are the outstanding issues?
- Q&A

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

Regulation of Medical Devices and IVDs in the UK

- Post Brexit
- End of the transition period
- The new UK Regulations

IVDs and companion diagnostics

- Implications and timelines
- New IVDR conformity assessment rules

Clinical evidence

- Key changes in generating clinical evidence
- Clinical evaluations
- Clinical investigations
- Case studies – what evidence for different devices

Combination products

- The new requirements

Increased vigilance and post market surveillance

- How to comply
- Q&A

Other essential considerations from the new legislation and future changes

- Impact of the pandemic

New Regulations for Medical Devices and IVDs in Europe

Schedule and prices

Three ways to book:

Online	Email	Telephone
management-forum.co.uk/2236	bookings@management-forum.co.uk	+44 (0)20 7749 4730

Ref	Date	Location	Price	Early booking price	Until*
12077	**30 Jun-1 Jul 2022**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60	GBP **1,099** + VAT = 1,318.80 EUR **1,579** + VAT = 1,894.80 USD **1,786** + VAT = 2,143.20	**26 May**
11726	**13-14 Oct 2022**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60	GBP **1,099** + VAT = 1,318.80 EUR **1,579** + VAT = 1,894.80 USD **1,786** + VAT = 2,143.20	**8 Sep**

Your choice of date & location

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Multiple booking discounts

Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.

* Note the early booking discount cannot be combined with any other offers or promotional code

The 'Small Print'

FEE

The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

PLEASE NOTE

Falconbury 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, Falconbury will refund the registration fee and disclaim any further liability.

TERMS AND CONDITIONS

The rest of the 'Small Print', the event cancellation policy and the terms and conditions are on our website, please visit management-forum.co.uk/content/terms-and-conditions