MANAGEMENT forum

This course qualifies for **6 CPD hours** for your Continuing Professional Development records

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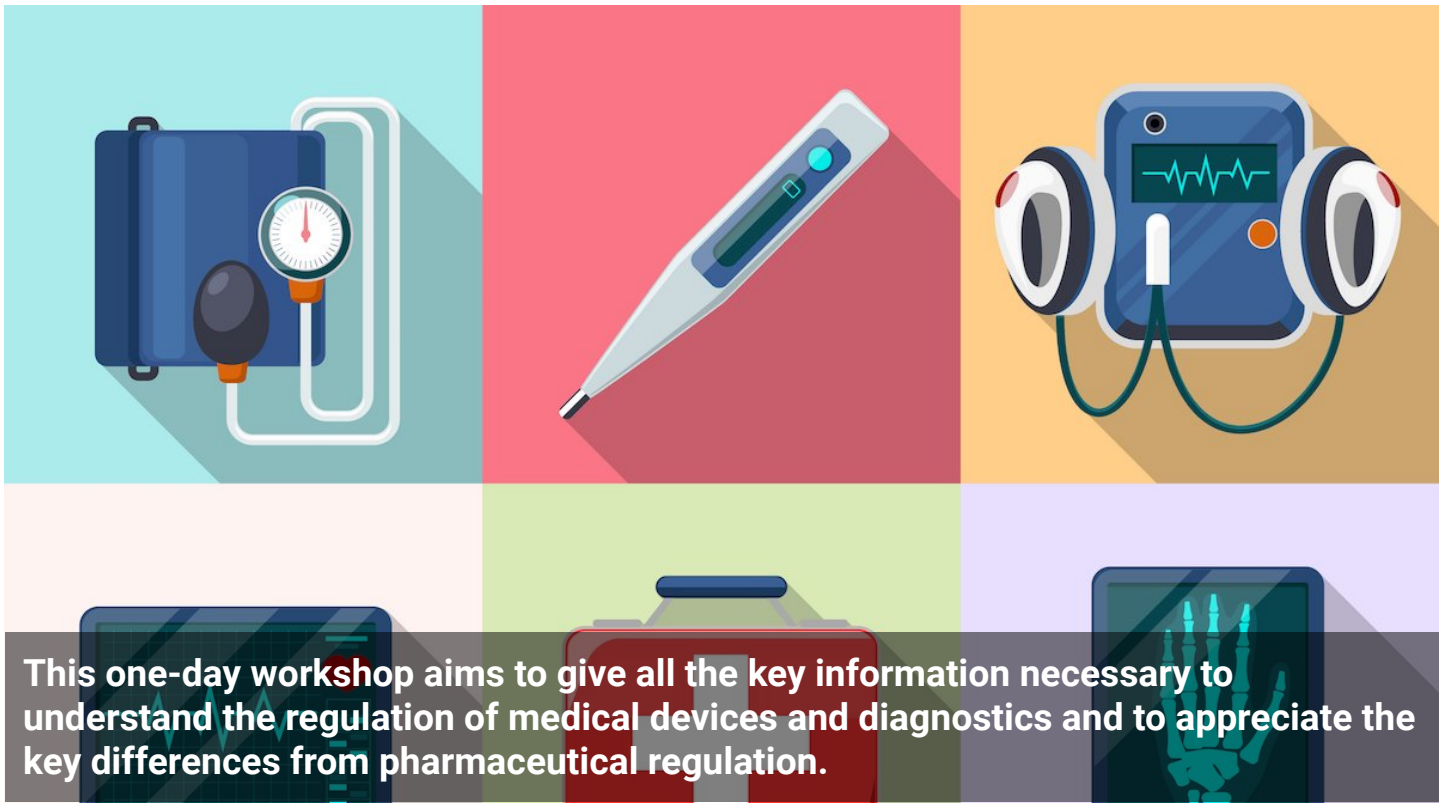
An Essential Overview of the Medical Device Industry

23 May 2022, London
+ 1 more date - see back page for full schedule



This one-day workshop aims to give all the key information necessary to understand the regulation of medical devices and diagnostics and to appreciate the key differences from pharmaceutical regulation.

Programme at a glance:

- What is a medical device and an IVD?
- How is the device market developing?
- An overview of the MDR and IVD Directives and the Regulations
- What are the key differences in approach from pharmaceuticals?
- Who are the key actors?
- The role of the competent authority and authorised representative
- Brexit update – impact on the medical device industry
- What is a Notified Body?
- How to work with a Notified Body
- How are medical devices and IVDs evaluated?
- What are the data requirements?
- Clinical trial controls for devices
- Device vigilance versus pharmacovigilance
- Device/drug combination products and companion diagnostics
- Building a global approval strategy on an EU CE mark approval
- The key interface with digital technology

Full programme inside

★★★ *"Theresa was an excellent presenter. She presented her topic on regulatory submission and notified bodies really well. The content was clear and she had a good engagement with the delegates."*

Yulia Degtyareva, Scientist, Philips

★★★★★ *"The course was delivered by highly educated industry experts who shared their extensive knowledge in a clear and entertaining manner. The delegate numbers were small which allowed for a very personal service. I will be recommending Management Forum courses to my colleagues."*

Stephanie Kirby, Senior Regulatory Affairs Officer, Bells Healthcare

★★★★★ *"Enjoyed the course, felt the topics were covered in enough detail given the subject matter. Informal atmosphere with a small number of delegates meant opportunity for questions which were welcomed. Both speakers were clearly passionate about their subject and this was evident during their presentations. "*

Gillian Hakewill, Regulatory Affairs Officer, SPD Development Company Limited

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Course overview

The medical device and diagnostics sectors are entering a period of regulatory change with implementation of the new Medical Device Regulation (MDR) in 2020. This interactive one-day course will provide you with the key information necessary to understand the regulation of medical devices and diagnostics, and to appreciate the key differences from pharmaceutical regulation. Our expert trainers will discuss the transition and implementation of the MDR and will cover the new rules and approaches to developing combination products. The important interface with digital technology will also be explored, alongside the impact of Brexit. There will be ample opportunity for discussion throughout the day to ensure you come away with a good understanding of the medical device industry.

Who should attend?

The course has been specifically designed to meet the needs of those working in pharmaceuticals and in allied business functions who need to understand the medical device sector. It will be particularly relevant for regulatory staff and those in clinical research, medical affairs and business development.

★★★★★ *"Both speakers were excellent and obviously knew their subject in great depth"*

Peter Davies, Quality Engineer, Bespak Europe Ltd

★★★★ *"Very nice overview"*

Camiel Kulker, Senior Regulatory Affairs Manager , Astellas Pharma Europe B.V.

★★★★★ *"The course is great for people having no idea about the medical device industry. Makes you understand the key differences between pharmaceuticals and medical devices in terms of regulations and vigilance."*

Francois Rugiero, Convergence Pharmaceuticals

Expert trainers

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.

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.

What is a medical device and an IVD?

How is the device market developing?

An overview of the MDR and IVD Directives and the Regulations

- Challenges of MDR implementation – May 2020
- Preparation for IVDR implementation

What are the key differences in approach from pharmaceuticals?

Who are the key actors?

The role of the competent authority and authorised representative

Brexit update – impact on the medical device industry

What is a Notified Body?

How to work with a Notified Body

How are medical devices and IVDs evaluated?

What are the data requirements?

Clinical trial controls for devices

Device vigilance versus pharmacovigilance

Device/drug combination products and companion diagnostics

- The operation of Article 117 and latest guidance

Building a global approval strategy on an EU CE mark approval

The key interface with digital technology

An Essential Overview of the Medical Device Industry

Schedule and prices

Three ways to book:

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management-forum.co.uk/2219

Email
bookings@management-forum.co.uk

Telephone
+44 (0)20 7749 4730

Ref	Date	Location	Price	Early booking price	Until*
11626	**23 May 2022**	Live webinar	GBP **599** + VAT = 718.80 EUR **859** + VAT = 1,030.80 USD **970** + VAT = 1,164.00	GBP **499** + VAT = 598.80 EUR **719** + VAT = 862.80 USD **814** + VAT = 976.80	**18 Apr 22**
11732	**2 Nov 2022**	Live webinar	GBP **599** + VAT = 718.80 EUR **859** + VAT = 1,030.80 USD **970** + VAT = 1,164.00	GBP **499** + VAT = 598.80 EUR **719** + VAT = 862.80 USD **814** + VAT = 976.80	**28 Sep 22**

Your choice of date & location

We can present this course on an in-house basis, tailored to your requirements, at your location and/or online. Contact us at inhouse@management-forum.co.uk or see inside the brochure for more details of how this can be a more cost-effective approach.

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