IPI Academy

MANAGEMENT forum

Presented by
Management Forum

A Regulatory Update on the Medical Device and In-Vitro Diagnostic Regulations in the EU and UK

22 October 2024

This course will provide an excellent opportunity to hear the latest developments from regulatory experts, and enable participants to discuss the implications of the regulations on working practices and the potential impact on future regulatory strategies.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Much has changed since the Medical Device Regulation (MDR) and the In-Vitro Diagnostic Regulation (IVDR) were adopted in May 2017.

This course will bring you fully up-to-date on:

- the rephrased implementations
- the new guidelines
- role and output from the Medical Device Co-ordination Group (MDCG)
- recent medical device regulatory developments in the UK

It will also consider future developments and the evolving role of the EMA.

This course will provide an excellent opportunity to hear the latest developments from regulatory experts, and enable participants to discuss the implications of the regulations on working practices and the potential impact on future regulatory strategies.

Benefits of attending

This is a must-attend workshop and has been designed for all those working or interested in the medical device and diagnostic market in the EU and the UK.

- **Explore** the changes in the UK regulation as its system becomes independent and moves away from the EU rules
- **Navigate** the increasingly complex world of device and diagnostic regulations
- **Gain insights** into future changes to the regulations and how "digital medicine" may be regulated in the future

Who should attend

Medical Device and In-Vitro Diagnostic professionals from the following areas:

- Regulatory affairs
- Clinical studies
- Vigilance
- Post Market Surveillance
- Quality systems
- Technical Support and Business Development

Programme

Welcome and introduction

- New features
- Key roles
- Key learnings

Overview of the current position with the MDR

- Where are we today?
- How have we got to this point
- The evolution of 'Digital Medicine' and its impact on the MDR

EU view from industry - Medical Devices

- What has been delivered
- What remains outstanding
- How will things progress
- Challenges and opportunities
- Notified Bodies and QMS

View from industry - IVDs

- What has been delivered
- What remains outstanding
- How will things progress - what are the transitional arrangements and how best to use them
- Challenges and opportunities
- Notified Bodies and Quality Mangement Systems (QMS)

Notified Bodies (NBs) and Conformity Assessment Bodies (CABs) - Update on progress from an NB perspective

- How many Notified Bodies/CABs are there?
- Role of the Medical Device Co-ordination Group (MDCG)
- Nando (New Approach Notified and Designated Organisations) Information System
- Implications of the MDR, Brexit and the Covid Pandemic
- UK Approved Bodies/CABs
- Differences and similarities between Notified Bodies and UK Approved Bodies
- How is the Conformity Assessment process working

Combination products

- EU Pharmaceutical Products influence
- New role of the European Medicines Agency (EMA) / Committee for Medicinal Products for Human Use (CHMP)
- Implications of MDR:Article II7

UK Regulatory proposals for medical devices and IVDs

- IDAP and Innovation in the UK
- MHRA roadmap for international recognition and domestic legislation
- MHRA roadmaps for AI/SaMD and IVDs
- UK regulations on post-market activities

Panel discussion

Presenters

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.

Ian Sealey

Ian Sealey graduated with a BEng (Hons) in Medical Engineering in 2003 and, after a taking a year out to study for a Graduate Diploma in Law, held health-related engineering and policy roles in the private sector, local government, and the National Health Service.

In 2012 he joined the Civil Service as a Medical Device Specialist at the Medicines and Healthcare products Regulatory Agency and, in 2015, was appointed assistant secretary at the Department of Health, with responsibility for running its Departmental Board.

Since leaving the Civil Service in 2017 he has provided regulatory, quality, technical, and policy consultancy services to multinational and start-up medical device and in vitro diagnostic medical device manufacturers. His specialist interests include the risk management of electromedical devices, multi-legislative CE marking, and training delivery.

Sue Spencer

Sue Spencer BSc (Hons) is Head IVD, Principal Consultant and UK Country Manager.

Sue leads Qserve's IVD service, she has over 37 years' experience in the Medical Device and IVD industries including extensive notified body experience.

Key areas of expertise include

- IVDD and IVDR regulations and transitions
- UKCA
- QMS implementation
- Internal, supplier and compliance audits
- Risk Management
- CDx
- Training
- Working with small start-up and multinationals
- Notified Body interaction

Sue has worked for several IVD companies ranging from start up to large multinationals, where she has held positions in R&D, manufacturing, and quality assurance. Sue worked for 3 notified bodies establishing two from scratch.

Sue has worked for Qserve for 4 years helping manufacturers transition to the IVD Regulation and leading a team specialising in both European and FDA submission and quality systems, with special interests in CDx.

Presenters

Theresa Jeary

Theresa Jeary is Principal Technical Specialist, Medicinal and Biologics, with BSi.

Theresa holds a Master's Degree in Pharmaceutical Science and is eligible to be a Pharmaceutical Qualified Person. She has over 25 years of 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 of Notified Body experience working at BSi as a technical expert and previously 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 is a frequently invited speaker on medical device legislation and combination products.

Stephen Lee

Steve joined ABHI as Director of Diagnostics Regulation in 2020.

After completing his degree in Biochemistry and Biology at Aston University, Steve trained as a Biomedical Scientist, working in hospital microbiology before moving to industry to work as company microbiologist. Steve joined MHRA in 1996 when it was still the Medical Devices Agency and when the IVD Directive had yet to be implemented.

While at MHRA, Steve worked with manufacturers, Notified Bodies, other Competent Authorities, Trade Associations, standards bodies and government departments. Steve was Chair of the European Commission's IVD working group when the IVD regulations where being developed.

In 2019, Steve was presented with the TOPRA award for regulatory excellence.

Course date

22 October 2024

Live online
09:30-17:00 **UK (London)** (UTC+01)
Course code 14382

GBP **549** ~~649~~
EUR **789** ~~929~~
USD **893** ~~1,049~~
Until 17 Sep

How to book

Online:
ipi.academy/2236

Alternatively contact us to book, or if you have any queries:

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

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
IPI Academy (and our training partners) 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, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

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

Lucie Green
QA Manager
Vyaire Medical Products
Sep 24 2019

★★★★★

Excellent training performed by very knowledgeable speakers.

Marie-Pierre Hontas
Senior Director Scientific & Clinical Affairs
Vexim SA – Stryker IVS
Mar 6 2019

★★★★☆

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.
Sep 24 2019

★★★★☆

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
Sep 24 2019

Run this programme in-house for your whole team

Coming to IPI Academy 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.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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