IPI Academy

MANAGEMENT forum

Presented by
Management Forum

An Introduction to the Medical Device Regulation

16-18 July 2025
+ 3-5 November 2025

This seminar provides a detailed introduction to the European medical device legislation. It will explain the Regulation and which products are covered, the involvement of Notified Bodies, how to choose one and outline what a manufacturer must do.

Format:
Live online

CPD:
18 hours for your records

Certificate of completion

Course overview

This seminar provides an invaluable overview of the European Medical Device Regulation (MDR). The interactive programme will explain the new legislation and which products are covered, the involvement of Notified Bodies and how to choose one and will outline a manufacturer's responsibilities. It will also cover the documentation necessary to apply for the CE mark.

This is an excellent introduction from leading experts in the field and delegates should expect three days of intensive training.

For a more advanced follow-on course from this, please see our Advanced Regulatory Affairs for Medical Devices which you may also be interested in.

Benefits of attending

- **Learn** an overview of EU regulations and the MDR
- **Understand** the classification and labelling system of medical devices
- **Explore** medical device vigilance
- **Gain** information on CE Marking
- **Clarify** drug/device combinations and devices incorporating material of animal origin

Who should attend?

Past delegates include those working in regulatory affairs, pharmacovigilance, quality assurance and technical support. This event will be of particular interest to all personnel who are new to the medical device industry, all those who intend to place a medical device on the market and anyone who requires an overview of the medical device sector.

Programme

Day 1

What is a medical device?

- Definition
- Examples

Europe and the MDR – overview of the regulations applicable for bringing a medical device to market

Economic operators and other parties

- Who are they?
- How do they interrelate?
- What are their responsibilities?

Classification of devices

- What are the classes and how do we classify devices?

Workshop: classification

Day 2

Manufacturers' responsibilities

- Technical file and design dossier requirements

Quality systems

- EN ISO 13485: 2012 and 2016
- The requirements for a quality system

Labelling of devices

- Use of language and symbols
- Instructions for use

Workshop: vigilance

Clinical evaluations

- European regulatory environment
- When are clinical investigations necessary?
- What is required by the competent authority, Ethics Committee and Notified Body?

Workshop: CE marking

Day 3

Medical device vigilance

- Adverse event reporting
- Reporting requirements
- Post-market surveillance (PMS)

Drug/device combinations

- Drug or device?
- Examples of classification

Devices incorporating material of animal origin

- Animal-derived materials legislation
- Directive 2003/32/EC

The revision to the regulations for medical devices

Presenter

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.

Course dates

16-18 July 2025	**Live online** 09:30-17:15 **UK (London)** (UTC+01) *Course code 15231*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 11 Jun**
3-5 November 2025	**Live online** 09:30-17:15 **UK (London)** (UTC+00) *Course code 15030*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 29 Sep**

How to book

Online:
ipi.academy/1990

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

Email:
info@ipiacademy.com

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

★★★★★

The webinar was presented very well with both speakers having a clear understanding of the changes and implications that the MDR will have. Both speakers were able to help with all questions with a clear understanding of their answers and applicability. Both speakers were very clear and very helpful with all questions and all parts were very informative, i really liked the workshops.

Louise Bateman
Senior Quality Assurance and Regulatory Affairs Manager
Bedfont Scientific Ltd
Nov 6 2023

★★★★★

Speakers are very knowledgeable about Medical Device products. Janette also gave us extra material that will help me navigate European regulations and explore new content.

Luciana Freddi
pharmaceutic

Nov 8 2022

★★★★★

Excellent course material/ presentations, clear, easy to understand and straight forward. Very welcoming and friendly speakers, with an open minded mentality to consider different regions in covering medical devices regulations. Would highly recommend the course for basic/intermediate level manufacturers and regulators.

Fajer K. Alkusair
Standards and Regulations Specialist - Medical Devices Sector
Saudi Food & Drugs Authority
Aug 1 2022

★★★★★

All 3 speakers were fantastic and I really liked that they were all coming from different sides of the industry, sharing their perspective on top of delivering the content

Julie Leone
Regulatory Affairs Manager
Haleon
Aug 1 2022

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.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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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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