IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Medical Device Studies: Clinical Evidence

Gathering and using clinical evidence for CE marking and post-market compliance in line with the new MDR.

Format:
Bespoke training

CPD:
12 hours for your records (depending on your requirements)

Certificate of completion

Course overview

Clinical evidence is crucial to bringing a device to market and is a very important aspect of post-market compliance to meet the requirements of current legislation. The collection of clinical data to demonstrate safety and performance is pivotal to CE marking a medical device and the collection of post-market data is key to the continued safety and performance considerations once the device is on the market.

This practical and intensive two-day course has been designed specifically for those who are involved in gathering clinical evidence required for medical devices. It will cover the full range of activities that should be applied during the collection of clinical evidence for both pre- and post-market studies and will also provide delegates with information on the European regulations for gathering clinical evidence and conducting medical device studies. Participants will benefit from advice and tips from industry experts on the practicalities of conducting studies within Europe as well as the types of clinical data to collect in order to be compliant with the new MDR.

Benefits of attending

- **Understand** the regulatory requirements and guidance applicable to clinical evidence
- **Clarification** on Clinical Evaluations (Literature Reviews)
- **Know** what is required in terms of clinical data prior to CE marking and post CE mark
- **Explore** what documentation is needed for the pre-and post-market phases of clinical data collection
- **Discover** how to conduct a clinical investigation and post market clinical follow-up study
- **Plan** how to prepare regulatory notifications to the competent authorities and obtain other necessary approvals
- **Learn** the key aspects of pre and post market study setup, management, monitoring and close down
- **Discuss** how to prepare a paper or presentation for publication and marketing
- **See** the differences between drugs and devices

Who should attend?

- Personnel involved in setting up, managing and monitoring studies
- Setting up, managing and monitoring studies
- R&D
- Marketing
- Regulatory affairs
- Those who conduct clinical evaluations/investigations/post market follow up studies
- Those moving from pharma to medical device studies

Reviews

★★★★★

I thoroughly enjoyed the 2 days and speaker is great. Although I am familiar and experienced in some of the areas covered, I still felt that I learnt new things. The Workshops were good and it was nice with only 4 of us on the course. I enjoyed the whole webinar a lot.

Jennine Walker
Clinical Affairs Manager
Dermal Laboratories Ltd
Oct 15 2025

★★★★☆

The presenters were incredibly knowledgeable in their subject areas and was able to convey complex information, in an easily digestible way. Overall, a very good summary of Clinical evidence for medical devices.

Hannah Vince-Drew
Clinical Research Supervisor
Bedfont Scientific
Jul 12 2023

★★★★★

Janette is a very good speaker; she is very prepared and provided lots of contents and information during these 2 days.

Giulia Carli
Global Clinical Affairs Programme Manager
Corin Ltd
Nov 24 2022

★★★★★

Good knowledge and information provided

Valerie Hart
Clinical Development Manager
Dermal Laboratories Ltd
Nov 24 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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