IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Clinical Evaluation of Medical Devices: The Clinical Evaluation Report

9-10 May 2024
+ 5-6 August 2024, 27-28 November 2024

Cover all the aspects of clinical evaluation in line with the European medical device regulations and applicable guidance documents

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

This two-day introductory course will cover all aspects of clinical evaluation in line with the European Medical Device Regulation (MDR) and applicable guidance documents. The programme will provide you with the tools and skills you will need to produce a high-quality clinical evaluation report (CER) for all your medical devices. You will understand the detail of what clinical data is needed, how to collect it, analyse it and receive direction on producing a CER that is acceptable to the regulatory authorities and Notified Bodies. You will learn how the process fits into the development of a medical device and also the post-market aspects of clinical evidence.

The programme includes case studies and template documents which you will be able to utilise to produce your own clinical data evidence documentation.

Benefits of attending:

- **Gain** a detailed overview of the clinical evaluation process
- **Understand** the concepts involved in conducting a clinical evaluation
- **Learn** how to utilise information gathered during a clinical evaluation
- **Take away** skills in conducting systematic literature searches
- **Understand** where clinical evaluation fits into the development and marketing of medical devices
- **Learn** how to appraise data
- **Know** how to assemble clinical evidence acceptable for review by regulatory authorities or Notified Bodies

Who should attend

- CROs
- Medical writers
- Clinical staff
- Those who conduct clinical evaluations/investigations/post-market follow-up studies
- Those moving from pharmaceuticals to medical devices

Personnel involved in:

- Gathering clinical evidence and conducting clinical evaluations
- R&D
- Regulatory affairs

Programme

Day 1

What is a Clinical Evaluation?

- Explanation of the terminology used in clinical evalutions
- Overview of a clinical evalution
- The importance of clinical evidence in medical device development

Why and When is it Necessary to Conduct a Clinical Evaluation?

- Where does clinical evaluation sit within the medical device process?
- Why is clinical evidence important?
- Who are the stakeholders in the process?

Who and What is Involved in the Clinical Evaluation Process?

- Overview of each step
- Use of equivalent products

Workshop : Bringing It Together

- An interactive exercise on what has been learnt so far

What Regulations Govern Clinical Evaluations and What Guidance Documents Should Clinical Evaluations Be Conducted To?

- An in-depth review of the available regulatory and guidance documents which can be utilised during the process and how to interpret these

Day 2

Documentation Necessary for Conducting a Clinical Evaluation

- The clinical evaluation plan

The Literature Review Process

- Selecting databases and conducting searches
- How to source data and review it
- How to clarify the question on which you need to find literature, including devising the most comprehensive literature search strategy and selecting key words

The Clinical Evaluation Report (CER)

- What is it and what is included?
- Who should write it?
- How to write it

What is State of the Art and how to Conduct a Risk Benefit Assessment of the Data?

- Performance and safety analysis
- State-of-the-art analysis
- Risk-benefit analysis

Impact of the Medical Device Regulations (MDR)

Presenter

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.

Course dates

9-10 May 2024	**Live online** 09:30-16:45 **UK (London)** (UTC+01) *Course code 13643*	GBP **1,299** EUR **1,869** USD **2,129**
5-6 August 2024	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 13855*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 01 Jul**
27-28 November 2024	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 14030*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 23 Oct**

How to book

Online:
ipi.academy/2380

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

★★★★★

I enjoyed the structure and the way the webinar is organized with a very knowledgeable and interesting speaker.

Emina Omeragic
Director Clinical Regulatory Affairs
TRiCares GmbH
Feb 26 2024

★★★★★

I am brand new to the CER world and was hoping to better understand the layout. Janette did a fantastic job helping me to accomplish this. She made it very easy to get a clear picture of the expectations of completing a CER.

Tena Green
Medical Writer/Clinical Consultant
SunMed LLC
Feb 26 2024

★★★★★

It was very organized and beautifully presented

Tena Green
Medical Writer/Clinical Consultant
SunMed, LLC
Feb 26 2024

★★★★★

Very kind and attentive

Nicolas Oviedo
Medical Affairs Specialist
Baxter Healthcare Corp
Feb 26 2024

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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