IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Clinical Evaluation of Medical Devices: The Clinical Evaluation Report

21-22 July 2025
+ 25-26 November 2025

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
- **Explore** 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

And 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)

Presenters

Steve Curran

A skilled research engineer, project manager and regulatory and quality assurance professional with an extensive background in manufacturing process engineering, medical device design and global regulatory and quality affairs for the medical device industry.
For 8+ years Steve worked as a Lead Auditor, Scheme Manager and Product Technical Expert for one of the leading European Notified Bodies, BSI Healthcare. Subsequently he became Head of Regulatory & Quality Affairs for a general medical devices group of companies handling all aspects of regulatory & quality affairs including management of submissions and audits for Notified Body, Competent Authority, FDA and global third party customers and suppliers, including onsite audits of these.
Steve held the position of Compliance Director of an orthopaedics medical device manufacturer based in the UK and USA. Currently he holds the position of Technical Director at Regulatory & Quality consultancy, Regulatus Ltd.
Steve's core skills are Technical documentation remediation, audits to ISO13485, MDSAP, MDR 2017/745, IVDR and 21 CFR 820 and other global requirements. He has delivered training content and training course delivery in process validation, risk management, ISO13485 and internal auditing, technical writing, design and other regulatory and quality initiatives. He holds accredited QQI Training delivery & Evaluation Grade 6 with Distinction.

Joanne E Stewart (James)

A multi- award-winning scientific innovator with strong commercial acumen and a proven track record across medical devices/pharmaceuticals. Up-to-date knowledge of the regulatory landscape including ICH-GCP, MDR-2017/745 and ISO14155. With a PhD in wound physiology, Joanne maintains a deep scientific background in wound care and a thorough knowledge of global competitor developments. She recently enjoyed 18 months as Director, Global Clinical Strategy for Smith & Nephew Ltd.

As a Consultant, Joanne provides strategic clinical development advisory and operations support, mostly to start-ups/SMEs in a variety of clinical indications including wound care, diabetes, inflammatory disease, ophthalmology and neuro-oncology.

She has contributed to significant acquisitions in the device arena: most recently and notably, she was instrumental in the patent generation, product development and clinical evidence generation which eventually led to the purchase of Thirty Technology's wound care franchise, by Convatec, in April 2023 for circa £176 M.

She retains an Honorary Senior Lectureship (Associate Professor) at the William Harvey Research Institute, Queen Mary University of London and additionally acts as Scientific Advisor to Ascension Life Fund and Science Angels Syndicate.

Course dates

21-22 July 2025	**Live online** 09:30-16:45 **UK (London)** (UTC+01) *Course code 14669*	GBP **1,499** EUR **2,099** USD **2,399**
25-26 November 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15100*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 21 Oct**

How to book

Online:
ipi.academy/2380

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 **30% 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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