IPI Academy

MANAGEMENT forum




*Presented by*
**Management Forum**

# Clinical Evaluation of Medical Devices: The Clinical Evaluation Report

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

**Format:**
Bespoke training

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

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

# 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

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★★★★★

**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

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★★★★★

**It was very organized and beautifully presented**

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

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★★★★★

**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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