MANAGEMENT forum

This course qualifies for **12 CPD hours** for your Continuing Professional Development records

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Clinical Evaluation of Medical Devices: The Clinical Evaluation Report

4-5 May 2022, Live webinar
+ 2 more dates - see back page for full schedule

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

Programme at a glance:

- What is a clinical evaluation?
- Why and when is it necessary to conduct a clinical evaluation?
- Who and what is involved in the clinical evaluation process?
- Workshop : Bringing it together
- What regulations govern clinical evaluations and what guidance documents should clinical evaluations be conducted to?
- Documentation necessary for conducting a clinical evaluation
- The literature review process
- The CER
- What is state of the art and how to conduct a risk benefit assessment of the data?
- Impact of the MDR

Full programme inside

★★★★★ *"Janette is very nice and friendly. She has a lot of relevant knowledge and experience about the clinical evaluation process and the report. I learned a lot form her!"*

Dror Sever, Senior Device Information Scientist, Novo Nordisk

★★★★★ *"I thought this was a terrific webinar, lead by an excellent topic expert, and I feel much more confident about participating and/or leading the CER update at my company."*

Juliana Pugmire, Clinical Research Consultant, Current Health

★★★★ *"It was overall a very good webinar that gave a nice overview of the Clinical Evaluation proces. A shame it had to be a webinar due to the Covid-19 situation, it would have worked better if we could all meet in person and also have small conversations in breaks and so on."*

Christina Frary, research audiologist, Demant

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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 produce 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

★★★★★ *"Everything was perfect."*

Amnah AlKhan, Regulatory Affairs Specialist, Gulf Health Council

★★★★★ *"Wonderful speaker, friendly and approachable. He manages to put a lot of information over in a short period, in a simple way, making it a lot easier to digest. Overall, an amazing teacher and incredibly knowledgeable in regulations concerning medical devices. I particularly liked the interaction and encouragement of the group activities and communication. An amazing course, well structured, and a knowledgeable, friendly and approachable speaker."*

Hannah Vince-Drew, Clinical Research Associate, Bedfont Scientific

★★★★★ *"Janette is excellent. Her knowledge and ability to clearly communicate in an engaging way about the topic at hand really mean that it's very easy to learn and understand what is being discussed. The workshops were very useful in cementing what you've learnt and also bouncing ideas around. Absolutely excellent, fantastic speaker, wealth of knowledge, discussion welcomed!"*

Alex Hyde, Senior Regulatory Affairs Specialist , Sinclair Pharma

Expert trainer

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.

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

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 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 MDR

Clinical Evaluation of Medical Devices: The Clinical Evaluation Report

Schedule and prices

Three ways to book:

Online
management-forum.co.uk/2380

Email
bookings@management-forum.co.uk

Telephone
+44 (0)20 7749 4730

Ref	Date	Location	Price	Early booking price	Until*
11677	**4-5 May 2022**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60	GBP **1,099** + VAT = 1,318.80 EUR **1,579** + VAT = 1,894.80 USD **1,786** + VAT = 2,143.20	**30 Mar**
11850	**8-9 Aug 2022**	Venue TBC	GBP **1,499** + VAT = 1,798.80 EUR **2,099** + VAT = 2,518.80 USD **2,338** + VAT = 2,805.60	GBP **1,299** + VAT = 1,558.80 EUR **1,819** + VAT = 2,182.80 USD **2,026** + VAT = 2,431.20	**4 Jul**
11793	**28-29 Nov 2022**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60	GBP **1,099** + VAT = 1,318.80 EUR **1,579** + VAT = 1,894.80 USD **1,786** + VAT = 2,143.20	**24 Oct**

Your choice of date & location

We can present this course on an in-house basis, tailored to your requirements, at your location and/or online. Contact us at inhouse@management-forum.co.uk or see inside the brochure for more details of how this can be a more cost-effective approach.

Multiple booking discounts

Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.

* Note the early booking discount cannot be combined with any other offers or promotional code

The 'Small Print'

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

Falconbury Ltd 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, Falconbury will refund the registration fee and disclaim any further liability.

TERMS AND CONDITIONS

The rest of the 'Small Print', the event cancellation policy and the terms and conditions are on our website, please visit management-forum.co.uk/content/terms-and-conditions