Clinical Evaluation of Medical Devices: The Clinical Evaluation Report

5-6 June 2019 • 26-27 November 2019 London

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
Understand where clinical evaluation fits in the development and marketing of medical devices
Take away skills in conducting systematic literature searches
Learn how to appraise data
Know how to assemble clinical evidence acceptable for review by regulatory authorities or Notified Bodies

Janette Benaddi
Independent Consultant to the Medical Device Industry

Expert trainer:

Highly recommend this one.
Shirley-Ann Van Der Spuy, Redline Pharmacovigilance Ltd

Expected content, clear presentation, very approachable speaker.
Teresa Lopes, Biotop Medical

Dates and venue
5-6 June 2019 26-27 November 2019
The Cavendish Hotel
81 Jermyn Street, London SW1 6JF
Tel: +44 (0)20 7330 2111
(Note: Entrance via Duke Street)

Programme schedule
Registration and refreshments: 09.00
Day one Day two
Start 09.30 09.00
Close 17.00 17.00

Accommodation
When available we have arranged a preferential rate for accommodation at the venue. To take advantage of this price, please mention that you are attending the Management Forum seminar when booking your accommodation.
http://www.thecavendish-london.co.uk/
enquiry.cavendish@the-ascott.com
For information on alternative accommodation, please visit our website: management-forum.co.uk/accommodation

Payment options
1. Invoice which can be paid by bank transfer or credit/debit card
2. Online through our secure website when registering

Earliest booking discount
£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2140.98

Full price
£1499.00 + VAT = £1798.80 • €2099.00 + VAT = €2518.80

Multiple booking discount for 2nd or subsequent delegates - 15%
£1274.15 + VAT = £1528.98 • €1784.15 + VAT = €2140.98

Early booking discount
Book before 3 May 2019

FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements, please advise customer services when booking.

Please note: Management Forum 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, Management Forum will refund the registration fee and disclaim any further liability.
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Introduction
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 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 clinical evaluation report 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 course includes case studies and template documents which you will be able to utilise to produce your own clinical data evidence documentation.

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 one**
09.00 ➤ Registration and refreshments
09.30 ➤ Welcome and introduction
  - Objectives and overview
09.50 ➤ What is a clinical evaluation?
  - Explanation of the terminology used in clinical evaluations
  - Overview of what a clinical evaluation is
  - The importance of clinical evidence in medical device development
10.35 ➤ Refreshments
11.00 ➤ 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?
12.30 ➤ Lunch
13.30 ➤ Who and what is involved in the clinical evaluation process?
  - Overview of each step
  - Use of equivalent products
14.30 ➤ Workshop: Bringing it together
  - An interactive exercise on what has been learnt so far
15.30 ➤ Refreshments
16.00 ➤ 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
16.30 ➤ Quiz
16.45 ➤ Q & A and wrap-up of day one
17.00 ➤ End of day one

**Day two**
09.00 ➤ Review of day one, introduction to the day, objectives and overview
09.10 ➤ Documentation necessary for conducting a clinical evaluation
  - The clinical evaluation plan
10.30 ➤ Refreshments
10.45 ➤ 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
12.30 ➤ Lunch
13.30 ➤ The clinical evaluation report (CER)
  - What is it and what is included?
  - Who should write it?
  - How to write it and what is included
14.30 ➤ 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
15.15 ➤ Refreshments
15.30 ➤ Impact of the Medical Device Regulation (MDR)
  - What do Notified Bodies (NB) look for when reviewing the report?
  - How to meet NB expectations
  - Quality assurance steps for the final CER
16.30 ➤ Quiz
16.45 ➤ Q & A and wrap-up
17.00 ➤ End of course

A certificate of attendance for professional development will be available to each participant who completes the seminar.

**In-house training**

Elements of this course are also available in-house and can be tailored to your specific needs.

Our expert comes to you, saving you time and money. For more information contact Aleksandra on +44 (0)20 7749 4730 or email: inhouse@management-forum.co.uk