Book before 5 October 2018
and SAVE £200 / €280

Clinical Evaluation of Medical Devices

To book online go to: **management-forum.co.uk/2380** W

Dates and venue

6-7 December 2018 **Ref: 10403**
5-6 June 2019 **Ref: 10421**

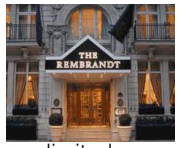
The Rembrandt Hotel
11 Thurloe Place
London SW7 2RS
Tel: +44 (0)20 7589 8100

Programme schedule

Registration and refreshments: 09.00

	Day one	Day two
Start	09.30	09.00
Close	17.00	17.00

Accommodation



We have arranged a preferential rate for accommodation at the venue. To take advantage of this please contact the hotel on the email below and state you are a Management Forum delegate. There are limited rooms available at this rate so please book early to avoid disappointment.

Email: reservations_rembrandt@sarova.co.uk
Web: www.sarova-rembrandthotel.com

For information on alternative accommodation please visit our website: **management-forum.co.uk/accommodation**

Three ways to book

management-forum.co.uk | info@management-forum.co.uk | +44 (0)20 7749 4730

Fees and payment

EARLY BOOKING DISCOUNT **Book BEFORE 5 October 2018**
£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2182.80

FULL PRICE **Book AFTER 5 October 2018**
£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

Payment options

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

In-house TRAINING

Management Forum In-house training

Coming to Management Forum 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.

To get a **FREE** consultation and to find out how we can work with you call **Aleksandra**, our in-house training expert, on **+44 (0) 20 7749 4730** or email ***inhouse@management-forum.co.uk***

To find out more please visit: ***management-forum.co.uk***

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.

For event cancellation policy and T&Cs see our website

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MANAGEMENT forum

Clinical Evaluation of Medical Devices: The Clinical Evaluation Report

6-7 December 2018 • 5-6 June 2019 London

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
- **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

Expert trainer

Janette Benaddi,
Independent Consultant to the Medical Device Industry

Includes Practical and interactive exercises

CPD CERTIFIED The CPD Certification Service

Clinical Evaluation of Medical Devices

6-7 December 2018 • 5-6 June 2019, London

Introduction

This two day course will cover all the aspects of clinical evaluation in line with the European Medical device regulations and applicable guidance documents. The course 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 high quality clinical data evidence documentation.

Who should attend

- CROS
- Medical writers

Personnel involved in:

- Gathering clinical evidence and conducting clinical evaluations
- R&D
- Clinical staff
- Regulatory affairs
- Those who conduct clinical evaluations/investigations/post-market follow up studies
- Those moving from Pharmaceuticals to Medical Devices

Expert faculty

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 organisations 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.

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

Programme

Day one

09.30 ▶ **Welcome and introduction**
- Objectives and overview

09.50 ▶ **What is a clinical evaluation?**
- Explanation of the terminology used in clinical evalutions
- Overview of what a clinical evalution 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 Regulations (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 forum**

In-house TRAINING

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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**