LIFE SCIENCE ACADEMY

How to Write a Clinical Evaluation Plan and Report

Find your way around the clinical evaluation of a medical device from concept to market approval and beyond

Type	Date	Language	Location
Corso online - Limited number	13, 15 and 16 May 2024	English	Online

ABOUT

Clinical evaluation of a medical device is a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.

The clinical evaluation plan (CEP) describes how the clinical evaluation will be performed, including objective and measurable clinical benefits, acceptability parameters for the benefit/risk profile, determination of what will be considered ‘sufficient clinical data’, what data will be collected and how any knowledge gaps might be addressed.
The CEP is regularly reviewed and updated and forms the basis of the clinical evaluation report (CER). The CER is an important part of the Technical File/ Design Dossier for a medical device. The medical writer conducts the literature review and compiles the CER with input from design engineers, regulatory specialists, safety scientists and quality experts.

The aim of this course is to better understand what is involved in developing a CEP and writing a CER to Medical Device Regulation (MDR) 2017/745 standards. The course will focus on the increased requirements of MDR and will cover the clinical evaluation process, literature reviews and post-market

surveillance (PMS) and benefit-risk assessment.

PROGRAMME

The course will be divided into 3 x 3-hours modules

MODULE 1: The Clinical Evaluation Plan (CEP)

- Regulations and guidelines
- How to go about the planning process
- What information to use and where to find it
- How to present the information in the CEP
- How to review and update the CEP

MODULE 2: State of the Art & Clinical Literature Reviews

- How to perform literature reviews as part of clinical evaluation
- How to determine the state of the art.
- How to present the clinical literature in the clinical evaluation report (CER)

MODULE 3: The Clinical Evaluation Report (CER)

- How to develop the CER
- Pre-clinical and clinical data
- Post-market surveillance activities, including Post-market clinical follow-up
- Risk Assessment
- Benefit-Risk Analysis

WHO SHOULD ATTEND

The course will be of interest to anyone involved with the clinical evaluation process and who contributes to the CEP and CER:

- Clinical Department managers
- Regulatory Affairs managers
- Marketing staff
- CROs

Participant experience
Experience of writing or contributing to a CER and awareness of the MDR 2017/745 would be useful.

TEACHING METHODS

The course format will be a slide presentation with the opportunity to ask questions, respond to

audience polls and participate in group exercises.

LECTURERS

Gillian Pritchard

Director, Sylexis Limited

Gillian is a pharmaceutical physician and regulatory medical writer with over 30 years' clinical and industry experience providing regulatory writing services to pharmaceutical and medical device clients. Gillian has broad pharmaceutical and medical devices experience across a wide range of therapeutic areas, e.g. cardiology, orthopaedics, clinical pharmacology, ophthalmology, diabetes and gynaecology. Over the years she has written numerous clinical study reports, clinical evaluation reports, literature reviews, clinical summaries and overviews, and various clinical trial documents. Gillian trained in medicine and was a research physician in academia and phase I-II contract research; a clinical project manager for phase III trials with Pfizer GRD; and also with a pharmaceutical and medical devices consultancy. She is a member of the Royal College of Physicians and Faculty of Pharmaceutical Medicine, has an MBA and an MSc in Clinical Pharmacology. Gillian is an active member of the European Medical Writers Association (EMWA) where she gives workshops on literature reviews, transferable skills in pharmaceutical and medical device writing, drug safety and ICH-GCP. She is a member of EMWA's medical devices special interest group.

AT THE END OF THE TRAINING, YOU WILL BE ABLE TO

- Have a better understanding of how to write an MDR-compliant CEP and CER

USEFUL INFORMATION

Online training – 3 modules

MODULE 1 | 13 May 2024 2:30 pm – 5:30 pm CEST
MODULE 2 | 15 May 2024 2:30 pm – 5:30 pm CEST
MODULE 3 | 16 May 2024 2:30 pm – 5:30 pm CEST

After the registration, you will receive all details about the connection.

The course will proceed with a minimum number of participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

REGISTRATION FEE

Early Bird: **€ 915,00*** until 22/04/2024

Ordinary: € 1.130,00*

Freelance – Individual – Academy – Public Administration**: € 585,00***

**for Italian companies: +22% VAT*

****Early Bird discount not applicable to Freelance – Individual – Academy – Public Administration fee

The fee includes: tuitions, organizational office assistance, teaching materials and attendance certificate that will be sent after the training via e-mail.

COURSE VENUE

Online interactive training on Zoom platform.
LS Academy will provide the access link to the virtual platform a few days before the training.