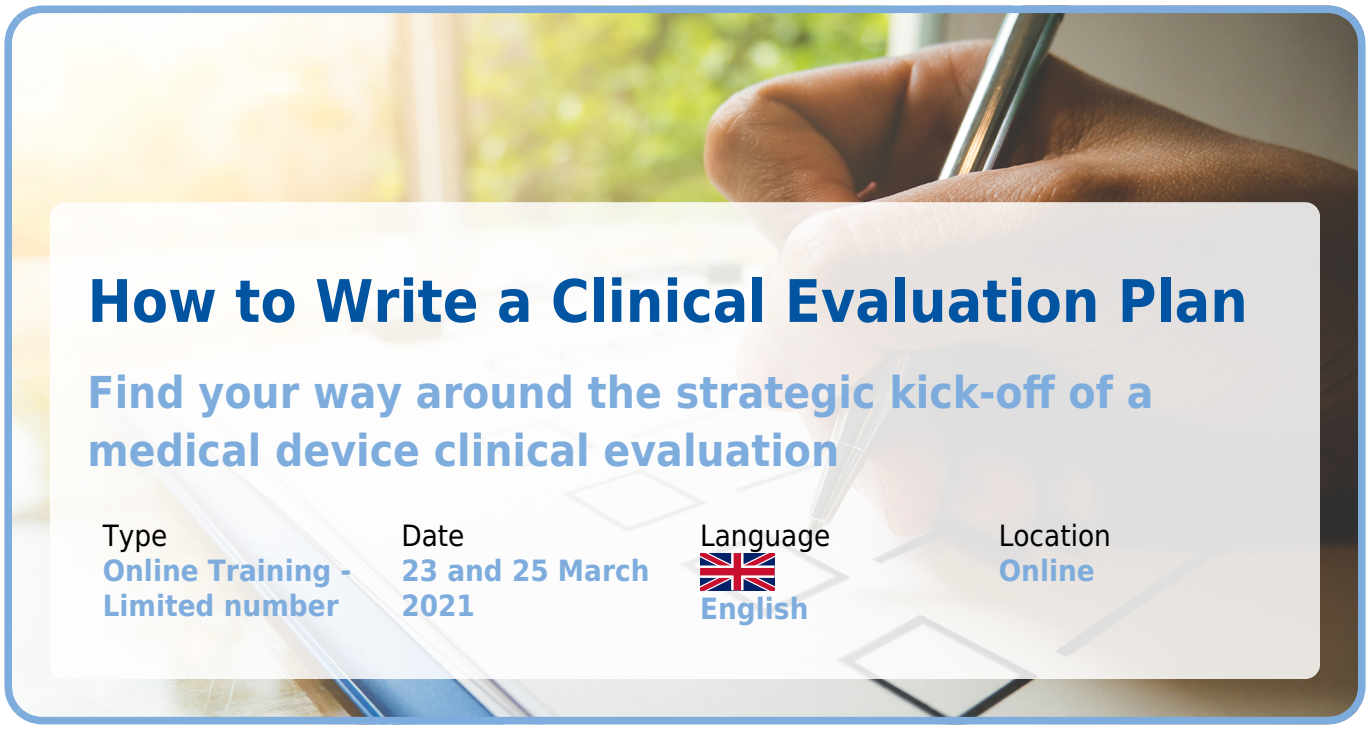
LIFE SCIENCE ACADEMY



How to Write a Clinical Evaluation Plan

Find your way around the strategic kick-off of a medical device clinical evaluation

Type	Date	Language	Location
Online Training - Limited number	23 and 25 March 2021	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 aim of this course is to explore what is involved in developing the CEP, including initial literature reviews and instructions for use (IFU).

PROGRAMME

The course will be divided into 2 X 3-hour modules spread over 1 week.

MODULE 1: Clinical Evaluation Plan

- 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 & Literature Review

- How to perform a literature review as part of clinical evaluation
- How to use this literature review in the CEP.

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
- Regulatory Affairs
- Marketing staff
- CROs
- Medical Writers

Attendees' experience
Experience of writing or contributing to a CEP or 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
- Know how to address the acceptability parameters for the benefit/risk profile
- Know how to set-up objective and measurable clinical benefits
- Know how to establish what is needed to decide on the concept of 'sufficient clinical evidence'
- Appropriately plan your clinical evaluation

USEFUL INFORMATION

Online training – 2 modules

March 23rd, 2021 2:00 pm – 5:00 pm CET
March 25th, 2021 2:00 pm – 5:00 pm CET

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: **€ 660,00*** (until 23 February 2021)

Ordinary: **€ 850,00***

Freelance – Academy – Public Administration**: **€ 430,00***

* for Italian companies: +22% VAT

**Early Bird discount not applicable to Freelance – 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.

SEDE DEL CORSO

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