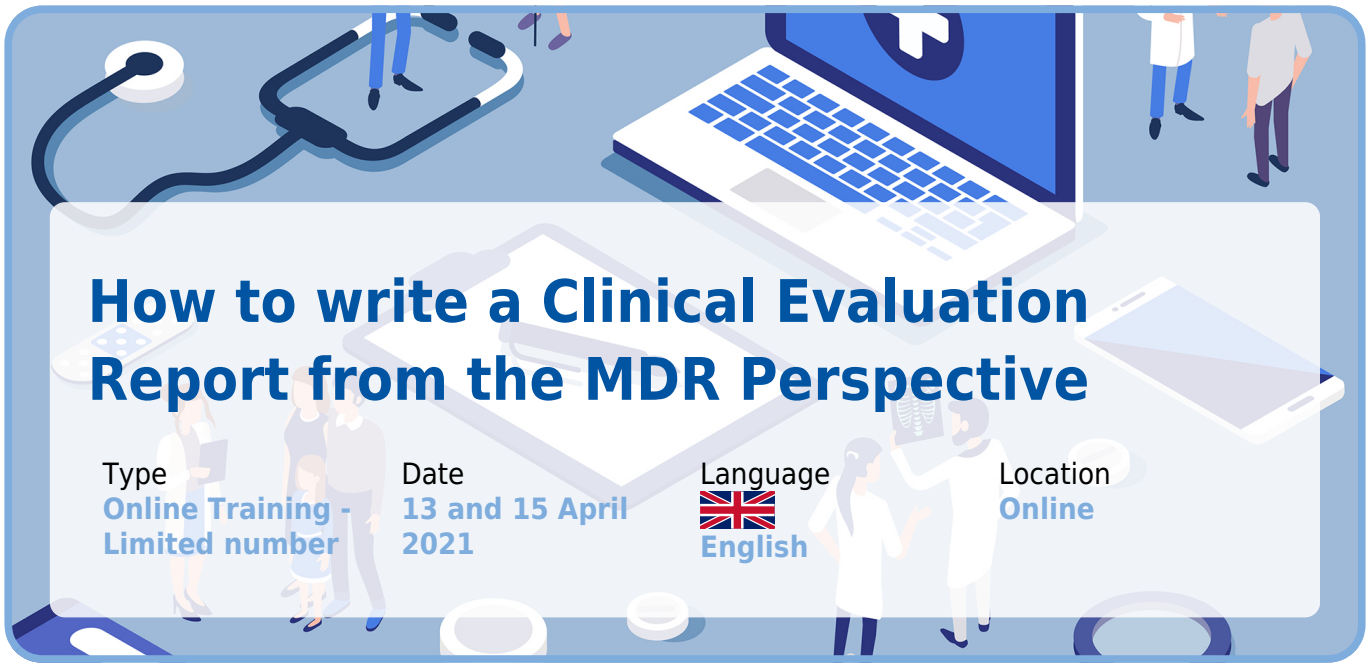
LIFE SCIENCE ACADEMY



How to write a Clinical Evaluation Report from the MDR Perspective

Type	Date	Language	Location
Online Training - Limited number	13 and 15 April 2021	English	Online

ABOUT

The clinical evaluation report (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 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 review and post-market surveillance (PMS) and benefit-risk assessment.

PROGRAMME

The course will be divided into 2 x 3-hour modules

MODULE 1: The Clinical Evaluation Report

- Introduction and course overview.
- Medical device directives, guidelines and regulations
- ISO 14155:2020 guideline
- MEDDEV 2.7/1 rev. 4 (2016) guideline
- Medical Device Regulation (MDR) 2017/745

- Medical Device Classification
- Clinical Evaluation Plan
- Clinical Evaluation Process
- Clinical Evaluation Report
- PMS Activities: MDR and MEDDEV 2.12/1 rev.8
- Periodic Safety Update Reports
- Post-market clinical follow-up: MDR and MEDDEV 2.12/2 rev. 2
- Risk Assessment
- Benefit-Risk Assessment

MODULE 2: Literature Review Part of CER

- Literature Review Protocol
- Literature Searches
- Current Knowledge / State of the Art
- Clinical Literature
- Literature Appraisal
- Data Extraction
- Clinical Literature Analysis

WHO SHOULD ATTEND

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

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

Attendees' 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 CER

USEFUL INFORMATION

Online training – 2 modules

April 13th, 2021 2:00 pm – 5:00 pm CET
April 15th, 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 16 March 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.