Medical Devices: a 5-Step Clinical Evaluation Masterclass

ABOUT

This 5-steps masterclass will cover all aspects of clinical evaluation in line with the European Medical Devices Regulation (MDR) 2017/745 and applicable guidance documents.

These 5 courses (33 hours of training) are designed to give you the tools and skills you need to clinically evaluate all your medical devices.

You will learn to find your way around the regulatory requirements and guideline documents. You will understand how to appropriately approach the strategic kick-off of a medical device evaluation in the Clinical Evaluation Plan. You will gain the insights of a Clinical Evaluation Report. You’ll discuss best practice on how to prepare Post-Market Clinical Follow-up Plans and Reports, as well as gain insights in common pitfalls and tips on how to prevent them. And finally, you will learn about the Summary of Safety and Clinical Performance, including skills for writing for lay audiences.

An opportunity to learn the insights of the Clinical Evaluation of medical devices through case studies, discussions and examples.

PROGRAMME

Learn your way around the requirements for the clinical evaluation of medical devices and the impact of the MDR and guideline documents on clinical evaluation through a
Clinical Evaluation for Medical Devices
24 and 25 February 2022; 9:30 am - 12:30 pm CET

The course describes how to prepare the new requirements from a clinical perspective including the MEDDEV 2.7.4/1 on clinical evaluation and the MEDDEV 2.12/2 on post market clinic follow up and MDCG Guidance on clinical evaluation for legacy devices, equivalence, sufficient clinical data. The training will allow participants to obtain a clear understanding of the regulatory requirements and will give hands-on insight on how to achieve compliance with respect to the changing environment and new documents to be created such as the summary of safety and clinical performance (SSCP) and periodic safety update reports (PSUR).

- Overview on Medical Devices requirements
- The MDR requirements
- Get ready to MDR from a clinical perspective
- MEDDEV 2.7/1 rev 4 and MDCG guidance on clinical evaluation
- MEDDEV 2.12/2 rev 2 on post market clinical follow up studies (PMCF)

Appropriately approach the strategic kick-off of a medical device clinical evaluation

How to Write a Clinical Evaluation Plan
01 and 03 March 2022; 2:00 pm – 5:00 pm CET

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).

- 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
- 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

And now? How do I get started on the Clinical Evaluation Report writing?

How to Write a Clinical Evaluation Report from the MDR Perspective
12 and 14 April 2022; 2:00 pm – 5:00 pm CEST
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 webinars 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.

- The Clinical Evaluation Report
  - 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
- 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

After your clinical evaluation report is ready, you need to plan post-market surveillance...

Knowing your Post-Market Clinical Follow-up (PMCF)
How to program the life-cycle of your device under the MDR 2017/745 requirements
17 and 19 May 2022; 9:00 am – 12:45 pm CEST

Each device (or device family) needs a specific PMCF Plan and results of PMCF activities are summarized in a PMCF Evaluation Report. These documents are subjects to predefined review cycles and depend on several other input documents. This course will give you profound insights into the regulatory requirements for PMCF, best practice advice on how to prepare PMCF Plans and Reports, as well as insights in common pitfalls and tips on how to prevent them.

- Introduction to Annex XIV Part B of EU MDR 2017/745 (Post-Market Clinical Follow-up)
- Structure and Content: The MDCG (Medical Devices Coordination Group) Guidance on PMCF Plans (2020/7)
Final steps... prepare to go public with a summary of your clinical evaluation!

The Summary of Safety and Clinical Performance (SSCP)
Tools and techniques to help you in balancing regulator’s expectations and manufacturers timelines
21 and 22 June 2022; 9:00 am – 12:45 pm CEST

To be able to work on your SSCP you need strong technical skills, but you also have to be able to translate the technical documentation into a language that is clear to a lay audience without any medical background. In addition, consistency with the Technical Documentation, different expectations from the manufacturer and the Notified Body and strict timelines are additional hurdles. This course will give you profound insights into the regulatory requirements for the SSCP, best practice advice on how to prepare the SSCP, as well as insights in common pitfalls and tips on how to prevent them.

- Introduction to Article 32 of EU MDR 2017/745 (Summary of Safety and Clinical Performance)
- Structure and Content: The MDCG (Medical Devices Coordination Group) Guidance 2019/9
- Input documents and review cycles
- How to provide relevant information for healthcare professionals
- How to summarize safety and performance data from different source documents
- How to write for a lay audience
- Best practice – data visualization

WHO SHOULD ATTEND

- Clinical Affairs staff
- Regulatory Affairs professionals
- Medical Writer
- Quality system and quality assurance personnel
- Technical and Medical Writers
- CROs
- Those who conduct clinical evaluations/investigations/post-market follow-up studies
- Professionals moving from pharmaceuticals to medical devices
TEACHING METHODS

Interactive workshop with exercises and application to participant’s daily activities.

LECTURERS

Katharina Friedrich
MD - Freelance Medical Writing Consultant
Katharina Friedrich is a medical writer with experience in MDR regulatory writing. She is based in Heidelberg, Germany and works as a Freelance Medical Writing Consultant with focus on orthopedic and cardiovascular devices. She prepares Clinical Evaluation Plans and Reports, PMCF Plans and Reports and SSCP in compliance with MDR 2017/745 for class I to class III devices. She also supports development projects and the conduction of PMCF activities. As medical doctor she has experience in the field of orthopedic and trauma surgery.

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.

Arkan Zwick
Corporate Regulatory Affairs Director at CROMA Pharmaceutical, Austria
Mr. Arkan Zwick is the Corporate Regulatory Affairs Director of CROMA Pharmaceutical, Austria. CROMA is a private global pharmaceutical and surgical company with products in ophthalmology, orthopedic and aesthetic dermatology. With more than eleven years of regulatory professional experience Arkan’s role includes regulatory advocacy for drug, medical device, combi products and cosmetic compliance projects as well as in house legal advice for contract management, merger and acquisition, and intellectual property projects. He is responsible for the company’s regulatory compliance in the EU working with several notified bodies and for global market authorizations in the Americas and Asia-Pacific. Arkan has a master’s degree in Law from the University of Vienna and a PhD in European Law. His expertise includes in house legal and regulatory consulting as well as lecturing at the University of Applied Sciences in Vienna and scientific board member and speaker on life cycle conferences and trainings. He is fluent in English, German and French.
AT THE END OF THE TRAINING PATH, YOU WILL BE ABLE TO

- Appropriately address the requirements for clinical evaluation for all classes of devices, regardless of risk classification
- Know how to establish measurable endpoints for clinical claims and guide a straight-forward literature search and source additional data
- Know how to avoid common pitfalls when addressing the benefit/risk profile of your medical device and be compliant with related requirements

USEFUL INFORMATION

The masterclass is made of a series of five standalone training courses. Visit each course online brochure for more information.

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

Each online training 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.

Number participants: 15 maximum each online training

REGISTRATION FEE

Early Bird: € 3.136,00* (until 27 January 2022)
Ordinary: € 3.690,00*

Freelance - Academy - Public Administration**: € 2.398,00*

* 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 for each training and attendance certificate that will be sent after the complete masterclass via e-mail.

TRAINING PATH VENUE

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