



LIFE SCIENCE[®]
ACADEMY

MASTERCLASS | Medical Devices: A 5-Steps Clinical Evaluation Masterclass

Type

Online Training -
Limited number

Date

From 16 February
to 17 June 2021

Language



English

Location

Online

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 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 regulatory overview.



+39 035.515684



info@LSacademy.com

www.LSacademy.com

- **Clinical Evaluation for Medical Devices**

16 and 18 February 2021

9:30 am - 12:30 pm CET (2 modules of 3 hours each, 6 hours in total)

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).

See full programme

<http://lsacademy.site-dev.it/en/product/clinical-evaluation-for-medical-devices/>

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

- **How to Write a Clinical Evaluation Plan**

23 and 25 March 2021

2:00 pm - 5:00 pm CET (2 modules of 3 hours each, 6 hours in total)

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).

See full programme

<http://lsacademy.site-dev.it/en/product/how-to-write-a-clinical-evaluation-plan/>

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

- **How to Write a Clinical Evaluation Report from the MDR Perspective**

13 and 15 April 2021

2:00 pm - 5:00 pm CET (2 modules of 3 hours each, 6 hours in total)

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.

See full programme

<http://lsacademy.site-dev.it/en/product/how-to-write-a-clinical-evaluation-report-from-the-mdr-perspective/>

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

18-19 and 20 May 2021

9:30 am - 12:00 pm CET (3 modules of 2.5 hours each, 7.5 hours in total)

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. See full programme

<http://lsacademy.site-dev.it/en/product/knowing-your-post-market-clinical-follow-up-pmcf/>

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**

15-16 and 17 June 2021

9:30 am - 12:00 pm CET (3 modules of 2.5 hours each, 7.5 hours in total)

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.

See full programme

<http://lsacademy.site-dev.it/en/product/the-summary-of-safety-and-clinical-performance-sscp/>

WHO SHOULD ATTEND

- Clinical Affairs staff
- Regulatory affairs professionals
- Technical and medical writer
- Quality system and quality assurance personnel
- 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.

Number participants: 15 maximum each online training.



LECTURERS



Katharina Friedrich
MD - Medical / Clinical Writer at BD (Becton Dickinson) - Peripheral Interventions

Katharina Friedrich is a medical writer with experience in MDR regulatory writing. She is based in Heidelberg, Germany and works for an international medical device company - Becton Dickinson. She is responsible for the preparation of Clinical Evaluation Plans and Reports, PMCF Plans and Reports and SSCPs 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, 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

Online training | 5-Steps Clinical Evaluation Masterclass

Clinical Evaluation for Medical Devices

16 and 18 February 2021 | 9:30 am - 12:30 pm CET

How to Write a Clinical Evaluation Plan

23 and 25 March 2021 | 2:00 pm - 5:00 pm CET

How to Write a Clinical Evaluation Report from the MDR Perspective

13 and 15 April 2021 | 2:00 pm - 5:00 pm CET

Knowing your Post-Market Clinical Follow-up

18-19 and 20 May 2021 | 9:30 am - 12:00 pm CET

The Summary of Safety and Clinical Performance (SSCP)

15-16 and 17 June 2021 | 9:30 am - 12:00 pm CET

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 26 January 2021)

Ordinary: € 3.690,00*

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

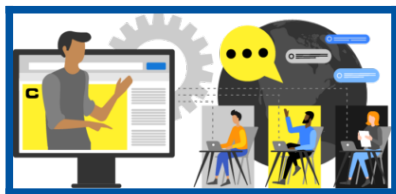
* for Italian companies: +22% VAT

**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.



SEDE DEL CORSO



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

