LIFE SCIENCE ACADEMY

Knowing your Post-Market Clinical Follow-up (PMCF)

How to program the life-cycle of your device under the MDR 2017/745 requirements

Type	Date	Language	Location
Online Training - Limited number	18-19 and 20 May 2021	English	Online

ABOUT

Post-Market Clinical Follow-up (PMCF) as part of Post-Market Surveillance is not a new requirement under the MDR. But requirements on how and when to do PMCF and on how to document these activities have been enforced. 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. The collection of clinical data is often time-consuming and expensive.
The PMCF Plan aims to organise well-considered PMCF activities to generate the missing data. To be able to work on your PMCF Plans, you need to know general and specific methods for PMCF, the input documents and the trigger for PMCF. The results presented in the PMCF Evaluation Report will also affect several other parts of the Technical Documentation.

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.

PROGRAMME

Module 1

- Virtual get together: Introduction of participants and the speaker, expectations towards the training
- 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)
- Input documents and review cycles
- Team discussion: Trigger for general and specific PMCF activities
- Take-home exercises

Module 2

- Different methods for PMCF
- Team work
- Practice: Writing a PMCF Plan for a fictional medical device
- Team discussion: Difficulties in writing a PMCF Plan for different device classifications
- Best practice – how to structure information from different sources in your PMCF Plan

Module 3

- Structure and Content: The MDCG (Medical Devices Coordination Group) Guidance on PMCF Evaluation Reports (2020/8)
- Practice: Summarize the PMCF activity results for a fictional medical device
- Team discussion: Difficulties in writing a PMCF Evaluation Report
- Common pitfalls and strategies to avoid them
- Open questions

WHO SHOULD ATTEND

Medical writers, Clinical Affairs, Quality Assurance, Product Managers.

Attendees' experience
This course is intended for personnel with little or no experience in regulatory writing, including PMCF Plans and PMCF Evaluation Reports, under the Medical Devices Regulation 2017/745 (EU MDR).

TEACHING METHODS

The workshop will be a mixture of presentations, team discussion, brainstorming and practical examples.

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.

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

- Understand the regulatory requirements for PMCF
- Identify the relevant input documents for your PMCF Plan
- Understand triggers for PMCF activities
- Prepare PMCF Plans for different device classifications
- Prepare PMCF Evaluation Reports and learn how to extract the most relevant information for these documents
- Understand common pitfalls with the preparation of PMCF Plans and PMCF Evaluation Reports and know how to avoid them

USEFUL INFORMATION

Online training – 3 modules

May 18th, 2021	9:30 am – 12:00 pm CET
May 19th, 2021	9:30 am – 12:00 pm CET
May 20th, 2021	9:30 am – 12:00 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: **€ 825,00*** (until 20 April 2021)

Ordinary: **€ 1.015,00***

Freelance – Academy – Public Administration**: **€ 536,00***

* 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.