LIFE SCIENCE ACADEMY

The Summary of Safety and Clinical Performance (SSCP)

Tools and techniques to help you in balancing regulator's expectations and manufacturers timelines

Type	Date	Language	Location
Online Training - Limited number	15-16 and 17 June 2021	English	Online

ABOUT

One of the new requirements of the MDR is to provide a Summary of Safety and Clinical Performance (SSCP), a document that is completely new to the medical device industry and that is unique in its structure and format: it is intended to include detailed information on a medical device for both healthcare providers and patients and will be available for the public. 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.

PROGRAMME

Module 1

- Virtual get together: Introduction of participants and the speaker, expectations towards the training
- 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
- Team discussion: Brainstorming on how to ensure consistency of the SSCP with the Technical Documentation
- Take-home exercises

Module 2

- Team work
- How to write for a lay audience
- Practice: Writing a lay summary of a clinical trial based on an example from ClinTrials.gov
- Team discussion: Difficulties in writing lay summaries
- Best practice – data visualization

Module 3

- Required information for the healthcare professional section
- Practice: Prepare a summary of safety information from different sources (PMS, Clinical Studies, literature data) for the SSCP
- Team discussion: Difficulties in writing a summary of safety data
- 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 the Summary of Safety and Clinical Performance, under the Medical Devices Regulation 2017/745 (EU MDR) and with little or no experience in the preparation of lay summaries.

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 the SSCP
- Identify the relevant input documents for the SSCP and learn how to extract the most relevant information
- Prepare lay summaries, including product description and summary of study results
- Prepare a summary of safety information for healthcare professionals
- Understand common pitfalls with the preparation of the SSCP and know how to avoid them

USEFUL INFORMATION

Online training – 3 modules

June 15th, 2021	9:30 am – 12:00 pm CET
June 16th, 2021	9:30 am – 12:00 pm CET
June 17th, 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 18 May 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.