LIFE SCIENCE ACADEMY

What You Need to Know about Medical Device Software and Never Dared to Ask

More than just apps – An introduction to Medical Device Software

Type	Date	Language	Location
Corso online - Limited number	25 and 26 October 2023	English	Online

ABOUT

Medical Device Software is a rapidly evolving field in the MedTech industry and requires specific considerations for the Clinical Evaluation Report and the State of the Art Evaluation.
MDCG 2019-11 helps with the specific classification rules for Medical Device Software, whereas MDCG 2020-1 provides recommendations for the clinical evaluation strategy. However, clinical evaluations for medical software can be less straightforward than for hardware devices.

The workshop will start with an introduction to the requirements of MDR 2017/745 on the clinical evaluation, including an overview of the relevant documents.

Participants will get a brief overview of the regulatory framework in the European Union for Medical Device Software. After that, we will take an in-depth look at how to discuss valid clinical association, technical performance, and clinical performance of Medical Device Software in the clinical evaluation.

The workshop will also discuss the challenges of writing State of the Art Evaluations, identifying benchmark parameters, and defining clinical benefits for Medical Device Software.
It will be an interactive training with team exercises and room for questions and discussions.

PROGRAMME

- Brief introduction to the requirements of MDR 2017/745 on the clinical evaluation, including an overview of the relevant documents
- Regulatory framework, classification rules, and relevant guidance documents
- Demonstration of valid clinical association
- Demonstration of technical and clinical performance
- Considerations for State of the Art Evaluations for Medical Device Software
- Challenges of identifying meaningful benchmark parameters and clinical benefits

WHO SHOULD ATTEND

The course is addressed to Clinical or Regulator Affairs Specialists, Medical Writers, or Product Managers.
The workshop will give an introduction to the regulatory framework of Medical Device Software in Europe (MDR 2017/745). Participants will learn about the specific considerations for the clinical evaluation for Medical Device Software.

Participant experience
Participants should have a good understanding of clinical evaluations for medical devices and should have experience in writing Clinical Evaluation Reports.
There is no need for experience with Medical Device Software.

TEACHING METHODS

Interactive training with a mixture of presentations and group exercises.

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 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 clinical evaluations for Medical Device Software
- Understand the content of MDCG 2020-1 with a focus on clinical evaluations
- Demonstrate the valid clinical association, technical performance, and clinical performance of

Medical Device Software in the Clinical Evaluation Report
- Plan and write State of the Art Evaluations for Medical Device Software
- Identify meaningful benchmark parameters for Medical Device Software

USEFUL INFORMATION

Online Training – 2 modules

Module 1 | 25 October 2023 from 09:30 am to 1:00 pm CEST
Module 2 | 26 October 2023 from 10:00 am to 12:30 pm CEST

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 13 October 2023)

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: tuition, organizational office assistance, teaching materials and attendance certificate that will be sent after the training via e-mail.

COURSE VENUE

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