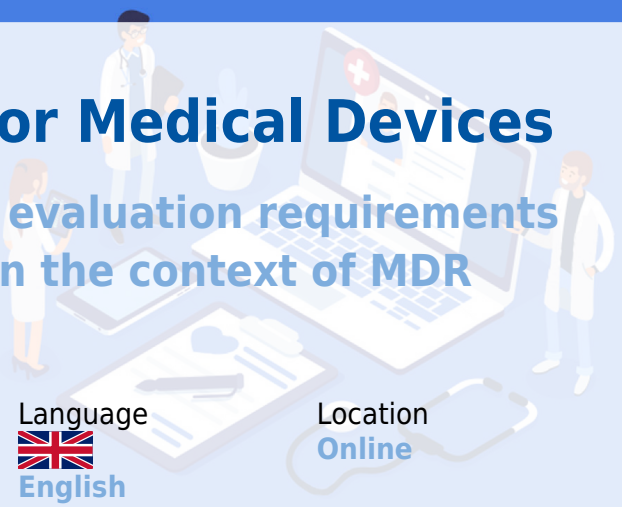
LIFE SCIENCE ACADEMY

Clinical Evaluation for Medical Devices

Understanding the clinical evaluation requirements for the MedTech industry in the context of MDR 2017/745



Type	Date	Language	Location
Online Training - Limited number	16 and 18 February 2021	English	Online

ABOUT

Significant regulatory changes are coming along with the EU Medical Devices Regulation 2017/745 (MDR), MEDDEV and MDCG (Medical Device Coordination Group) guidance evolutions affect the clinical evaluation of medical devices.

This online course gives participants an overview on the requirements for sufficient clinical data for medical devices and the impact of the MDR and guideline documents on clinical evaluation. The course further 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, and 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).

PROGRAMME

MODULE 1
Part 1: Overview on Medical Devices requirements

- MDD vs MDR, what is new?
- News on MEDDEVs, Standards, MDCG guidance
- The ISO 14155:2019 revision
- NB Guidelines on clinical evaluation
- Impact on product claims and marketing

Part 2: The MDR requirements

- MDR in a nutshell
- Clinical evaluation and investigation
- Equivalence approach

Part 3: Get ready to MDR from a clinical perspective

- Gap analysis
- Clinical strategy
- Processes and strategy with NBs

MODULE 2
Part 4: MEDDEV 2.7/1 rev 4 and MDCG guidance on clinical evaluation

- Overview and NB key points
- Good practice for equivalence justification including MDCG 2020-5
- Sufficient clinical evidence for legacy devices MDCG 2020-6
- Risk assessment and clinical

Part 5: MEDDEV 2.12/2 rev 2 on post market clinical follow up studies (PMCF)

- Overview on PMSP, PMSR, PSUR, CER, PMCF
- When to conduct PMCF
- PMCF plan and evaluation report templates MDCG 2020-8 and 7.
- Role of the NB

Case studies / Q&A

WHO SHOULD ATTEND

- CEO/CTO´s
- Regulatory Affairs
- Quality Assurance
- Clinical Department
- Marketing or Business Development responsible

Attendees' experience
Knowledge of the medical device directive MDD 93/42 is an advantage. Newcomers are welcome.

TEACHING METHODS

Online training with case study discussion and Q&A sessions.

LECTURERS

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

- Understand content of the new Medical Devices Regulation and its impact on the clinical evaluation of medical devices
- Understand new elements in ISO 14155 and MDCG guidance
- How to achieve compliance during the transition period
- Use practical experience from industry perspective

USEFUL INFORMATION

Online training – 2 modules

February 16th, 2021	9:30 am – 12:30 pm CET
February 18th, 2021	9:30 am – 12:30 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: **€ 720,00*** (until 19 January 2021)

Ordinary: **€ 910,00***

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: 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.