LIFE SCIENCE ACADEMY

Combination Products under the EU Medical Devices Regulation (MDR)

A targeted training to understand the regulatory pathway for device drug and drug device combinations in the European Union (EU). Updates from the MDR 2017/745 and EMA guidance

Type	Date	Language	Location
Corso online - Limited number	19 and 20 June 2024	English	Online

ABOUT

Significant regulatory changes came along with the EU Medical Devices Regulation (MDR) 2017/745 (MDR) and evolutions affecting pre-clinical and clinical modules of medical device dossiers, their market approval process and notified bodies involved in the conformity assessment.

Also, due to research and innovation, the varieties of Device-Drug and Drug-Device Combination Products is growing.

This workshop:

- Gives you an overview of the requirements for combination products under the MDR
- Guides you through the regulatory conformity pathways for combination products
- Gives you a clear understanding of the regulatory requirements for devices containing medicinal substances, devices provided in combination with drug products, devices combining software and medicinal products, and devices associated with natural substances.
- Gives hands-on insight on how to achieve compliance and the requirements for regulatory

documentation and CE marking

PROGRAMME

MODULE 1
Understanding combination products

- Definitions in device and drug regulations.
- How are combination products classified?
- Separate worlds, however approaching.
- Case studies.

Medical Devices Regulation 2017/745

- Introduction to MDR.
- Transition for industry and notified bodies.
- Key changes for the industry.
- Latest updates.

MODULE 2
Device conformity assessment

- What is conformity assessment?
- Process for CE marking and technical dossier and changes.
- How to demonstrate compliance to safety and performance requirements (GSPR).
- Case study – Syringe.

Device Drug combinations

- Guidance and conformity assessment.
- How is the European Medicines Agency (EMA) involved?
- Technical documentation drug part.
- Changes to the medicinal substance.

Drug Device combinations

- Impact of MDR Article 117 and EMA Guidance.
- Technical Documentation and Notified Body Opinion (NBO).
- Device data in the drug CTD.
- Changes.

WHO SHOULD ATTEND

This course is beneficial for professionals from both pharmaceutical and medical devices companies working in Quality Assurance, Regulatory Affairs, Clinical Operations, Medical Writing, Research &

Development, CEO / CTO.
The course will benefit to industry, pharma and biotech companies, CROs, Research Centres and Universities applied sciences and biotechnology faculties involved in development, manufacturing and sales of DDCPs.

Participant experience
Knowledge of the Medical Devices Directive (MDD 93/42) and of the Medical Devices Regulation (MDR) 2017/745 is an advantage. Newcomers are welcome.

TEACHING METHODS

The training includes knowledge transfer, interactive sessions, case studies and group discussions.

LECTURERS

Arkan Zwick
Corporate Regulatory Affairs Director at CROMA Pharmaceutical
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 the content of the MDR and its impact on the conformity assessment of devices
- Understand the requirements for combination products and the registration process to obtain CE marking and notified body option (NBO)
- Understand the impact of Art. 117 MDR and gain practical experience on the life cycle of products

USEFUL INFORMATION

Online Training – 2 modules

MODULE 1 | 19 June 2024 9:30 am – 12:30 pm CEST
MODULE 2 | 20 June 2024 9:30 am – 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: € 680,00* (until 22 May 2024)

Ordinary: € 875,00*

Freelance – Individual – Academy – Public Administration:** € 445,00*

* *for Italian companies: +22% VAT*

**Early Bird discount not applicable to Freelance – Individual – 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.

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.