The EU Regulation 2017/745 on Medical Devices

Understanding the Regulation and its impact on Industry

Type	Date	Language	Location
Corso online - Limited number	20-21-22 October 2020	English	Online

ABOUT

The EU Regulation on Medical Devices 2017/745 (MDR) changes significantly the landscape for the medical device industry. Beyond the familiar framework of the Medical Devices Directive 93/42 based on general requirements for safety and performance, harmonized standards, risk classification, the new Regulation introduce novel requirements in key areas such as stronger Notified Body Oversight, improved General Safety and Performance Requirements, Publicity of data, Clinical Requirements and Post Market Surveillance as well as labelling requirements. The Regulation also introduces a new responsible person for regulatory compliance (PPRC) for manufacturers and additional duties for importers and distributors. The Regulation further brings new evaluation procedures for high-risk devices and scrutiny of conformity assessments.

This online training gives Industry a detailed understanding of the new requirements and insight into how to prepare the end of the transition period in May 2021. With this course, participants will get a clear picture of the new requirements, understand the transition timelines and insure compliance to the new landscape.

PROGRAMME

Module 1 | 2:00 PM to 6:00 PM CEST

Understanding the MDR 2017/745

- Overview
- MDR vs. MDD
- Key changes
- Opportunity or threat?

Transition Period and Notified Bodies

- Transition for manufactures and industry
- Transition period for notified bodies
- Current state of designation procedure for notified bodies
- Notified body selection considerations

Walkthrough the MDR

- Preamble, Chapters, Annexes
- Latest MDR amendments and consolidated text
- MDCG guidance updates

Recap / Q&A

Module 2 | 2:00 PM to 6:00 PM CEST

Classification and conformity assessment

- Classification rules and conformity assessment procedures
- Clinical evaluation consultation of certain class III and IIb devices and scrutiny
- Clinical evaluation and investigation rules
- Device Drug / Drug Device Combinations (DCCP)

Person responsible for regulatory compliance

- Qualification requirements
- Duties
- Organizational impact

Technical Documentation

- Content of Technical Documentation
- General Safety and Performance Requirements (what is new)
- Labelling requirements

Recap / Q&A

Module 3 | 2:00 PM to 6:00 PM CEST

Post market requirements (PMS)

- Overview of post market requirements
- Periodic Safety Update Reports (PSURS)
- Summary of Safety and clinical Performance (SSCP)
- Impact on Distributors and Importers

Latest updates on the MDR

- NB designation process
- EUDAMED
- MDR implementation status rolling plan

Recap / Q&A

WHO SHOULD ATTEND

QA Managers, Regulatory Affairs Managers, Clinical Trail Managers, R&D Managers, CEO / CTO´s of companies working for medical device manufacturers, pharma and biotech companies, CROs, Research Centres and Universities applied sciences and biotechnology faculties.

Attendees' experience

Knowledge of the Medical Device Directive MDD 93/42 is necessary.

TEACHING METHODS

The training includes knowledge transfers, interactive sessions, case studies and tool kits helpful for MDR implementation.

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 the content of the new Medical Devices Regulation
- Understand the impact on your organization and products
- Use tools for the implementation of MDR in your company

USEFUL INFORMATION

Online Training – 3 modules

October 20th, 2020	2:00 PM – 6:00 PM CEST
October 21st, 2020	2:00 PM – 6:00 PM CEST
October 22nd, 2020	2:00 PM – 6:00 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: **€ 1.280,00*** (until 29 September 2020)

Ordinary: **€ 1.390,00***

Freelance – Academy – Public Administration**: **€ 730,00***

* 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.