Labelling Requirements for Medical Devices

Understanding the regulatory labelling requirements for medical devices in the context of the MDR 2017/745

Type	Date	Language	Location
Corso online - Limited number	18 and 19 November 2020	English	Online

ABOUT

Significant regulatory changes come along with the EU Medical Devices Regulation 2017/745 (MDR) and standards evolutions affects the labelling of medical devices.
This online course gives participants an overview on the requirements for medical devices labelling and the impact of the MDR and guideline documents on product labelling activities. The course further describes how to prepare to the new requirements from a regulatory labelling perspective.
The training will allow participants to obtain a clear understanding of the regulatory labelling requirements and will give hands on insight on how to achieve compliance.

PROGRAMME

Day 1 | 2:00 pm – 5:00 pm CET

Module 1: Overview on labelling requirements

- MDD vs MDR, what is new?

- Labelling Standards and Guidelines
- National laws

Module 2: The MDR requirements

- MDR and transition in a nutshell
- What is new for labelling?
- Risks of mislabelling

Day 2 | 2:00 pm – 5:00 pm CET

Module 3: Get ready to MDR from a labelling perspective

- General requirements Annex I MDR
- Instructions for use (IFU)
- Label
- Sterile barrier
- UDI & EUDAMED

Module 4: Symbols to be used in labelling

- New symbols state of play
- Symbols to be developed under MDR
- Next steps

Module 5: Implant device and hazardous substances

- Implant cards
- Hazardous substances labelling

Summary and Recommendations / Q&A

WHO SHOULD ATTEND

Regulatory Affairs, Labelling Department, Quality Assurance, Clinical Department, Marketing or Business Development responsible working for medical device manufacturers, pharma and biotech companies, CROs, Research Centres and Universities applied sciences and biotechnology faculties.

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

TEACHING METHODS

The training includes knowledge transfers, interactive sessions, case studies 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 content of the new Medical Devices Regulation and its impact on the labelling
- How to achieve compliance before the end of transition period
- Use practical experience from industry perspective
- Industry expert overview on the new MDR requirements
- Hands on experience on high risk devices and how the implement compliance in your company
- Latest news from MDR developments including IDU and EUDAMED

USEFUL INFORMATION

Online Training – 2 modules

November 18th, 2020 2:00 pm – 5:00 pm CET
November 19th, 2020 2:00 pm – 5:00 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: **€ 720,00*** (until 28 October 2020)

Ordinary: **€ 830,00***

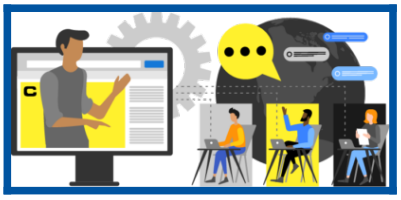
Freelance – Academy – Public Administration**: **€ 430,00***

* 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.