Labelling Requirements for Medical Devices under the Medical Devices Regulation 2017/745 (MDR)

A one-day training to understand medical device Labelling requirements under the MDR 2017/745

08 October 2020 - Vienna

110 € Early Bird discount
for enrolment by 10/09/2020

Course Language: English

Vienna

Austria

Thursday 08 October 2020

08:30-17:00

*Taking part in our training courses, you support **"The Vase of Flowers"** project*

For additional information: +39 (0)35.515684 | training@LSacademy.com www.LSacademy.com

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Why take this course?

The EU Medical Devices Regulation 2017/745 (MDR) has brought significant regulatory challenges. These standards also affect the essential requirements for Instructions for Use and Labelling. This course gives you an overview on the requirements for the information accompanying medical devices, necessary to identify the device itself and the manufacturer, together with all relevant safety and performance information for end users or other persons.
A hands-on insight on how to achieve MDR compliance in terms of Instructions for Use and medical device Labelling requirements!

To whom it may concern

Quality Assurance, Regulatory Affairs, Clinical Operations, Labelling Department, Medical Writing, Research & Development, CEO / CTO´s working for medical device manufacturers, pharma and biotech companies, CROs, Research Centres and Universities applied sciences and biotechnology faculties.

Type of Training

5 training Modules
Case studies
Q&A

Course Language

The course will be in English

Participant experience

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

Update 12.03.2020

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Programme

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Module 1: Overview on Labelling requirements

- MDD vs 2017/745 MDR, what is new?
- Medical device Labelling Standards and Guidelines
- National laws

Module 2: The MDR essential requirements

- 2017/745 MDR and transition period in a nutshell
- What is new for Labelling?
- Risks of mislabelling

Module 3: Get ready to MDR from a Labelling perspective

- General requirements – 2017/745 MDR Annex
- Instructions for use (IFU)
- Labels
- Sterile barrier
- UDI label & EUDAMED

Module 4: Symbols to be used in Labelling

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

Module 5: Implantable devices and hazardous substances

- Implant cards
- Hazardous substances Labelling

Summary and Recommendations / Q&A

Agenda

8.30-9.00		Participants registration
9.00		Course commences
10:30 – 10:45		Coffee Break
12.30		Lunch
15:00 – 15:15		Coffee Break
16.30 - 17.00		Q&A and Conclusion

Update 12.03.2020

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Lecturer

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 ophthal mology, 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. He is a lecturer at the University of Applied Sciences in Vienna and speaker on life cycle conferences. 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 (MDR) and its impact on Instructions for Use and medical device Labelling
- How to achieve compliance before the end of the MDR transition period
- Use practical experience from an industry perspective

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TO REGISTER FOR THE COURSE YOU CAN FILL IN AND SEND

THE REGISTRATION FORM OR DIRECTLY **REGISTER ONLINE:**

REGISTRATION FEES:

- ☐ Early bird: **€ 880,00*** until 10/09/2020
- ☐ Ordinary: **€ 990,00***
- ☐ Freelance – Academy – Public Administration**: **€ 490,00***

***For Italian companies: + 22% VAT**

The fee includes: tuition, teaching materials, lunches and coffee breaks, organizational office assistance, attendance certificate.

****Early Bird discount not applicable to Freelance – Academy – Public Administration fee**

Methods of payment

The full amount must be paid on registration to EasyB s.r.l by bank transfer or by credit card. If paying by bank transfer please attach proof of payment to the registration form. Bank transfer payable to:

EasyB S.r.l.

Via Roma, 20 - 24022 Alzano Lombardo (BG)

P. IVA **03633040161**

Banco BPM - Filiale di Carobbio Degli Angeli

IBAN: **IT81 F 05034 53960 000000003450**

SWIFT CODE: **BAPPIT21AY5**

For additional information:

Organisational Office	**Ilaria Butta**	+39 (0)35.515684	ilaria.butta@LSacademy.com
Scientific Manager	**Valeria Quintily**	+39 329.4683329	valeria.quintily@LSacademy.com

Please fill in and send: **(+39) 035.4501262** | **training@LSacademy.com**

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Invoicing details

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Address _____

Mail address (If different) _____ **Post code** _____

City _____

VAT number _____ **Invoice recipient code** _____

Terms & conditions

Terms of payment The registration fee must be paid at the time of registration. Confirmation of course admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants.

Cancellation Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the course date. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities. LS Academy reserves the right not to accept registrations not compatible with the event's target audience.

The course will proceed with a minimum of 8 participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

In accordance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, we inform you that EasyB S.r.l. (with headquarter in Via Roma 20, Alzano Lombardo, Bergamo, Italy, VAT number IT03633040161) will use your personal data voluntarily provided by you only with the consent and in compliance with the principles dictated by the European Regulations on the protection of personal data for sending newsletters, for marketing purposes (sending advertising material, market research and commercial communication) and for communication purposes to third parties (lecturers), also for marketing goals. You can read the complete information, including your rights and the procedures for the exercise of the same, following this link.

Update 12.03.2020

LSACADEMY.com **Date** _____ **Signature** _____