The Medical Device Clinical Evaluation

Understanding the clinical evaluation requirements for the MedTech industry.

Latest news from MDR 2017/745 and ISO 14155!

7 July 2020 - Copenhagen

110 € Early Bird discount

for enrolment by 09/06/2020

Course Language: English

Copenhagen

Denmark

Tuesday 7 July 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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Introduction

Significant regulatory changes have come along with the EU Medical Devices Regulation 2017/745 (MDR) and MEDDEV evolutions affecting the medical device clinical evaluation. This course gives participants an overview on the requirements for the clinical evaluation of medical devices and the impact of the MDR and guideline documents on clinical activities. Get prepared for 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!

A clear understanding of the regulatory requirements will give you an important tool to be fully compliant.

To whom it may concern

Quality Assurance, Regulatory Affairs, Clinical Operations, 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

Course Language: English

Module 1: Overview on Medical Devices requirements

- MDD vs MDR, what is new?
- Clinical MEDDEVs and Standards
- The reviewed ISO 14155:2019
- NB Guidelines
- Impact on product claims and marketing

Module 2: The MDR requirements

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

Module 3: Get ready to MDR from a clinical perspective

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

Module 4: MEDDEV 2.7/1 rev 4 on clinical evaluation

- Overview and NB key points
- Good practice for equivalence justification
- Risk and clinical assessment

Module 5: MEDDEV 2.12/2 rev 2 on PMS

- PMSP, PMSR, PSUR, CER, PMCF
- When to conduct PMCF
- Role of the NB

Case studies / 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

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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 the content of the MDR and its impact on the medical device clinical evaluation
- Understand new elements in ISO 14155
- Understand how to achieve compliance during the transition period
- Take advantage of the practical experience from industry expert

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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 09/06/2020
- ☐ 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**

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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.

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