Medical devices and clinical evaluation

Understanding the clinical evaluation requirements for the medtech industry

Tuesday **16 April** 2019 - Barcelona

110 € Early Bird discount
for enrolment by **18th March 2019**

Course Language: English

H10 Urquinaona Plaza

Plaça Urquinaona, 2
E-08010 Barcelona, Spain

Tuesday 16 April 2019

09:00-18:00

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

The most significant regulatory changes coming along with the EU Medical Devices Regulation 2017/745 (MDR) and MEDDEV evolutions affects the clinical evaluation of medical devices.

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. The course further describes how to prepare 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. The training will allow participants to obtain a clear understanding of the regulatory requirements and will give hands on insight on how to achieve compliance.

Who is the course aimed at?

The course will benefit to:

- CEO/CTO´s
- Regulatory Affairs
- Quality Assurance
- Clinical Department
- Marketing or Business Development responsible

Participant Experience

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

Teaching methods

Interactive training with case studies a Q&A sessions

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Programme

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Module 1: Overview on Medical Devices requirements

- MDD vs MDR, what is new?
- Clinical MEDDEVs and Standards
- 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

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

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

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

9:00 - 9:30		Participants registration
9:30		Course commences
11:00 - 11:15		Coffee Break
13:00		Lunch
15:45 - 16:00		Coffee Break
18:00		Q&A and conclusion

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Lecturer's Bio

Mr. Arkan **Zwick** *is Corporate Regulatory Affairs Director* of a private global pharmaceutical and surgical company with products in ophthalmology, orthopaedic and aesthetic dermatology. With more than eleven years, regulatory professional experience Arkan´s role includes regulatory advocacy for drug, medical devices and cosmetic projects as well as in house legal advice for contract management, merger and acquisition and intellectual property. He is responsible for regulatory compliance in the EU working with different notified bodies and for global market authorizations in the Americas and Asia-Pacific. Arkan has a graduate master's degree in Law from the University of Vienna and a PhD in European Law. He has been assigned as lecturer at the University of Applied Sciences in Vienna and as speaker on life cycle conferences and trainings. He is fluent speaker 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 clinical evaluation of medical devices.
- ✓ How to achieve compliance during the transition period.
- ✓ Use practical experience from industry perspective

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TO REGISTER FOR THE COURSE YOU CAN FILL IN AND SEND **THE REGISTRATION FORM**

OR DIRECTLY **REGISTER ONLINE:** https://clinicalevaluetionmd-2019.lsacademyevents.it/orders/new

REGISTRATION FEES:

- ☐ Early bird: **€ 850,00 *** until 18/03/2019
- ☐ Ordinary: **€ 960,00***
- ☐ Freelance – Academy – Public Administration: **€ 460,00***

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

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

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:

Secretarial office LS Academy	**Phone** +39 (0)35.515684	**Fax** +39 035.4501262	**Mail** training@LSacademy.com

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

Surname _____ **Name** _____

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Tel. _____ **Fax.** _____

E-mail _____

Special Dietary Requests _____

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.

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