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LIFE SCIENCE ACADEMY

1st MedDev Day

PRE-CONFERENCE WORKSHOP

How to write a Clinical Evaluation Report for an MDR Perspective

SOLD OUT

Monday, **September 23rd**, 2019

CONFERENCE

MedDev Day

Tuesday, **September 24th**, 2019

Vienna, Austria

NH Danube City

Wagramer Strasse 21

1220 Vienna

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A portion of the proceeds from this event are donated to the ***"Vase of Flowers" project.***

Pre-Conference **Workshop**

· **Monday, September 23rd, 2019**

How to write a Clinical Evaluation Report from MDR Perspective

Introduction

The clinical evaluation report (CER) is an important part of the Technical File/ Design Dossier for a medical device. Although the medical writer conducts the literature review and compiles the CER, input is required from several disciplines: engineers, regulatory specialists, safety scientists and quality experts all play vital roles. The aim of this workshop is to better understand what is involved in writing a CER to MDR standards and how the different disciplines can contribute to the CER writing process. The workshop will focus on the increased requirement for compliant CERs based on the evolution of the MEDDEV documents and the MDR. It will combine analysis of the new regulatory requirements per product risk class with real life examples on do's and don'ts when planning and writing CERs.

Who is this course for?

This workshop will be of interest to anyone involved with the clinical evaluation process and who contributes to the CER:

- Clinical Department managers
- Regulatory Affairs managers
- Marketing staff
- CROs

Type of Training

The workshop will be a mixture of presentation, group work and discussion.

Lecturer's Bio

Gillian *is a pharmaceutical physician and regulatory medical writer* with over 30 years' clinical and industry experience providing regulatory writing services for pharmaceutical and medical device clients. Gillian has broad pharmaceutical and medical devices experience across a wide range of therapeutic areas, e.g. cardiology, orthopaedics, clinical pharmacology, ophthalmology, diabetes and gynaecology. Over the years she has written numerous clinical study reports, clinical evaluation reports, clinical summaries and overviews, and various clinical trial documents. Gillian trained in medicine and was a research physician in academia and phase I-II contract research; a clinical project manager for phase III trials with Pfizer GRD; and also with a pharmaceutical and medical devices consultancy. She is a member of the Royal College of Physicians and Faculty of Pharmaceutical Medicine, has an MBA and an MSc in Clinical Pharmacology. Gillian is an active member of the European Medical Writers Association (EMWA) where she gives workshops on literature reviews, transferable skills in pharmaceutical and medical device writing, drug safety and ICH-GCP. She is a member of EMWA's medical devices special interest group.

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Programme

1. Introductions and workshop overview
2. Overview of clinical evaluation and clinical investigation requirements of the MDR, MEDDEV 2.7/1 rev4, MEDDEV 2.12/2 rev 2 and ISO 14155
3. Brief overview of medical devices classification. Risk class and notified body expectations on clinical data and summary of clinical documents related to each risk class
4. Stages of clinical evaluation
   - Scoping and planning – the clinical evaluation plan: What is "sufficient clinical data"? When are clinical studies necessary? When can I claim equivalence?
   - Identifying and appraising pertinent data
   - Analysis of clinical data
5. The CER layout and content, with particular focus on:
   - Current knowledge and state of the art
   - Equivalence justification
   - Clinical literature review
   - Risk assessment
   - Post-market surveillance (PMS) and post-market clinical follow-up (PMCF)
   - Update from ISO 14155
6. Discussion on participants' real life examples
7. Summary and Conclusions

Agenda

13:00 - 13:30		Participants registration
13:30		Course commences
15:15 - 15:30		Coffee Break
17:15 - 17:30		Q&A and conclusion

Participant experience

Experience of writing or contributing to a CER and awareness of the MDR 2017/745 would be useful.
Participants should be familiar with MEDDEV 2.7/1 rev. 4 (2016), particularly Appendix A9, as this will be referred to during the workshop.

At the end of the training, you will be able to...

...know how to write a CER and what should be included in it.

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MedDev Day

Since the European Union Medical Devices Regulations 2017/745 (MDR) entered in force, economic operators have been having busy times in adapting their processes and documentation in order to ensure compliance to the MDR requirements by its date of application (DOA) in May 2020. For the economic operators the challenge of the MDR comes together with revisions of the clinical investigation ISO standard as well as notified bodies building additional clinical expertise and undergoing their designation under the MDR. In this challenging regulatory environment, anticipation of changes and reorganisation of clinical evidence and clinical teams plays a pivotal role to maintain CE marking or acquire new registrations.

The first MedDev Day

gives insight into changes in the clinical regulatory environment for medical device industry with a focus on:

- Latest developments of the MDR implementation regulation and notified body designation process.
- Insights on clinical team structure and how to adapt to regulatory changes.
- Successful clinical evaluation plans and related clinical documents such as post market clinical follow up (PMCF) plans and reports, post market surveillance (PMS) documentation, periodic safety update reports (PSURS) and summary of safety and performance characteristics (SSCP).
- Design and statistical considerations for successful clinical evaluations in the medical devices world.
- How to comply with post market surveillance (PMS) requirements from a clinical perspective.

MedDev Day combines a pre-conference workshop on clinical writing with a comprehensive overview on changes affecting the device industry all together with exchange of expertise and workshops. It brings together quality, regulatory, clinical experts from Medical Devices and Pharma industry, CROs, Regulatory Authorities and Academia to share winning strategies, best practices and examples.

Scientific Board

Arkan Zwick
Corporate Regulatory Affairs Director
at CROMA

Anna Bottura
Business Development Manager
at Arithmos

Laura Michellini
Scientific Director
at Contract Research Organizations Latis Srl and Elle Research Srl

Who should attend?

The event is addressed to professionals dealing with Medical Devices, belonging to department such as:

- Regulatory Affairs
- Device vigilance
- R&D
- Medical Affairs
- Clinical Operations
- Statistics

from Pharmaceutical, Biotechnology and Medical Device companies, CROs, Universities/Hospitals, Academic Research, Patient Associations and Healthcare Organizations

MedDev Day

08:30 - 08:50	**Registration and Welcome coffee**
08:50 - 09:00	**Welcome from the scientific board** **Anna Bottura -** *Business Development Manager* at Arithmos **Laura Michellini -** *Scientific Director* at Contract Research Organizations Latis Srl and Elle Research Srl **Arkan Zwick -** *Corporate Regulatory Affairs Director* at CROMA
09:00 - 09:30	**The current understanding of Industry of the developments in the implementation of the Medical Devices Regulation** **Dario Pirovano** - *Senior Regulatory Adviser* at MedTech Europe
09:30 - 10:00	**Latest developments in Notified Bodies designation** **Dipl.-Ing. Hans-Heiner Junker -** *Senior International Affairs Manager* at TÜV SÜD Product
10:00 - 10:30	**The road to MDR compliance: role and set-up of the clinical team** **Edo Knijff -** *Sr. Clinical Affairs Manager* at Orthofix
10:30 - 11:00	**The New MDR: Safety By Design And By Vigilance** **Jan Bart Hak -** *Head Medical Device Team* at ProPharma Group
11:00 - 11:30	**Coffee break**
11:30 - 12:00	**ISO 14155 revised version: implications and possible effects of the MDR** **Danielle Giroud -** *Founder & CEO* at MD-Clinicals & WMDO
12:00 - 12:45	**The new Clinical Evaluation Process: approaches and strategies** **Fabio Macchi -** *Medical Device Design & development Manager, Clinical Evaluation Manager* at Helsinn Healthcare SA
12:45 - 13:00	**Q&A session**
13:00 - 14:00	**Networking lunch**
14:00 - 15:00	**How to approach clinical evaluation plan? Be ready for 2020** **Cristina Cavalli -** *Quality & Regulatory Affairs Manager* at Relife Srl
15:00 - 15:30	**Coffee break**
15:30 - 16:00	**Validation of Machine Learning based diagnostic devices and biomarkers** **Rajat Mukherjee -** *Senior Director, Principal Consultant, Data Science and Strategic Consulting* at Cytel Inc.
16:00 - 16:30	**Data collection for post market surveillance: methods and lessons learned from pharma** **Massoud Toussi -** *Global pharmacoepidemiology and drug safety lead* at IQVIA
16:30 - 16:45	**Q&A session and Conclusion**

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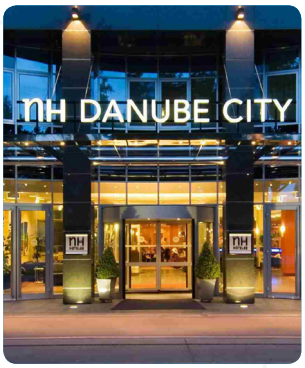
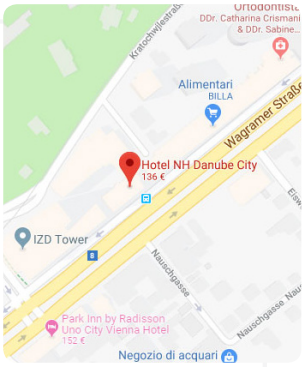
HOW TO REACH THE CONFERENCE VENUE



Venue

NH Danube City

Wagramer Strasse 21
1220 Vienna - Austria



From Airport to Hotel: distance 20km

Taxi average time: 15 - 30 min. and around 30-40 EUR

Public transportation:

S-Bahn: Take the S7 to the Praterstern station. Chnage onto the U (red line) towards Leopoldau. Get off the metro at the Kaisermühlen- Vienna International Center station. Take the Wagramer Straße exit and walk around 500 m away from the city center to reach the hotel.

Bus: Vienna Airport Lines buses stop directly opposite the arrival halls exit and with drop you off at the stop right in front of the hotel.

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Download the **Events Summary** 2019

For further information

Please visit the conference website or contact the organisational offices:

Ilaria Butta Phone: +39 (0)35.4123594 | ilaria.butta@lsacademy.com

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OPIS

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YOUR ROADMAP TO

MDR COMPLIANCE

seQure
Safety, Quality and Regulatory Services for Life Sciences

seQure can support medical device companies on the journey to MDR 2017/745 compliance with Quality Assurance and SOP support, Portfolio Rationalization, Device-Vigilance and supporting technology including MDR compliant EDC, safety system and document management system.

Our Core Services

- Pharmaco and Device Vigilance
- Regulatory Affairs
- Quality Management System
- Computer System Validation

REGISTRATION FORM - CHOOSE YOUR TICKET TYPE

Pre-Conference **Workshop**

- Monday, September 23rd, 2019

Conference

- Tuesday, September 24th, 2019

- REGISTRATION FEE FOR THE

WORKSHOP + CONFERENCE

SOLD OUT

- ☐ **€ 1.090,00* Super Early Bird fee** until June 28th, 2019
- ☐ **€ 1.170,00* Early Bird fee extended until September 02nd, 2019**
- ☐ **€ 1.[illegible]* Ordinary fee** (after September 02nd, 2019)
- ☐ **€ [illegible]* Patronage members fee** (please specify _____)
- ☐ [illegible] Academy, Public Administration, Freelance

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

The fee includes: seat at the workshop, informative literature for the 1/2 day, coffee break, organisational office assistance, certificate of attendance. Seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, networking lunch, coffee break, organisational office assistance, certificate of attendance.

- REGISTRATION FEE FOR THE

WORKSHOP

SOLD OUT

- ☐ **€ 660,00* Early Bird fee extended until September 02nd, 2019**
- ☐ **€ 770,00* Ordinary fee** (after September 02nd, 2019)
- ☐ **€ [illegible]* Patronage members fee** (please specify _____)
- ☐ [illegible] Academy, Public Administration, Freelance

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

The fee includes: seat at the workshop, informative literature for the 1/2 day, coffee break, organisational office assistance, certificate of attendance.

- REGISTRATION FEE FOR THE

CONFERENCE

- ☐ **€ 670,00* Early Bird fee extended until September 02nd, 2019**
- ☐ **€ 790,00* Ordinary fee** (after September 02nd, 2019)
- ☐ **€ 580,00* Patronage members fee** (please specify _____)
- ☐ **€ 430,00*** Academy, Public Administration, Freelance

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

The fee includes: seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, networking lunch, coffee break, organisational office assistance, certificate of attendance.

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Two ways to register

- **Online**

  please register here

  https://meddevday2019.lsacademyevents.it/orders/new

  In this case, you can choose to pay

  by credit card or by bank transfer

- By **email o fax**

  please fill the registration form below for each attendee

  and send it by **email : ilaria.butta@lsacademy.com**

  or by **fax : +39(0)35.4501262**

  In this case, you can pay by bank transfer.

PAYMENT BY **BANK TRANSFER**

The full amount must be paid on registration to EasyB S.r.l by bank transfer. If you pay 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 (Bergamo)

VAT: IT03633040161

BANCO BMP – Filiale di Carobbio degli Angeli

IBAN: IT81 F 05034 53960 000000003450

SWIFT Code: BAPPIT21AY5

For any additional information, please contact:

Ilaria Butta | ilaria.butta@LSacademy.com **Phone:** +39 (0)35.4123594

Surname _____ Name _____

Company _____ Job title _____

Address _____

City _____ Post code _____

Phone _____ Fax. _____

E-mail _____

Special Dietary Requests _____

I wish that my data (name, surname, job position and company) are inserted in the list of attendees distributed the day of the event ☐ Yes ☐ No

Invoicing details

Company name _____

Address _____

Mail address (If different) _____ Post code _____

City _____

VAT number _____ Invoice recipient code _____

Terms & Conditions

Terms of payment Payment should be made online (by credit card) or by bank transfer, at the time of registration. Confirmation of event admission will be given on receipt of payment. Invoice will be sent following receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants or registrations of roles that are not included in the target of the event.

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 event 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.

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Date _____ Signature _____

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