LIFE SCIENCE ACADEMY

Advanced European Regulatory Affairs

Update on Regulatory Affairs developments in Europe and the impact on product development and life cycle management

Type	Date	Language	Location
Online Training - Limited number	19-27 November, 1-4 December 2020	English	Online

ABOUT

During this regulatory affairs online training, you will get an advanced introduction and insight into the challenging environment of EU regulatory legislation and a practical advice for future regulatory affairs projects. In addition, an update on the latest developments and impact on the daily activities of a pharmaceutical company will be provided. As a result of the training you should be able to avoid pitfalls and compliance issues with the latest European regulations and optimize the effectiveness of your Pharmacovigilance system.

PROGRAMME

MODULE 1 by Lidia Canovas – 19 November
Understanding the new regulatory procedures – What's new in Regulatory Affairs?

- Expedited Pathways: What happened during Covid-19 emergency?
- Falsified Medicine Directive and impact on Regulatory Affairs
- Brexit

MODULE 2 by Lidia Canovas – 27 November
EU Procedures, CMDh guidance and Q&A documents (2 hours)

- National Procedure/MRP/DCP/CP
- Variations and Renewals

MODULE 3 by Remco Munnik – 1 December
Electronic Submission in EU
Current and future Telematics program and in-sight in the background and current status on ongoing projects:

- Telematics strategy 2021-2025
- eCTD
- CESP/Gateway
- eAF
- xEVMPD
- ISO IDMP
- ePI

MODULE 4 by Lidia Canovas – 4 December
Advanced Regulatory Affairs in EU

- Orphan Drug Designation
- Pediatric Investigation Plans
- Scientific Advice / Protocol Assistance
- IMPD and IB
- ATMPS: cells, tissue, organs, gene therapy, cloning
- Biosimilars

Review of the European Regulatory Affairs legislation

- Managing strategies based on European Regulatory Affairs

WHO SHOULD ATTEND

The course is addressed to Regulatory Affairs Manager, Officer and Specialist, Quality Manager, Development Pharmacist, Pharmacovigilance Manager, Project Manager working for pharmaceutical companies and CROs.

Participants' experience
Participants need to have a basic understanding of EU regulatory procedures.

TEACHING METHODS

Presentations, including practical sessions of business cases and questions from audience.

LECTURERS

Lidia Canovas

Director of Regulatory Affairs at Asphalion S.L.

Lidia has a Pharmacy and MBA degree. She has more than fifteen years overall experience in pharmaceutical industry, most of which as Regulatory Affairs Director, but she has also covered the role of Vice-Director for Research and Development. She has worked at Asphalion for ten years as General Manager and Director of Regulatory Affairs. In this second role, Lidia is responsible for the overall quality of the Regulatory and Scientific services that Asphalion provides to a large number of international and national clients.

Remco Munnik

Associate Director at Iperion, The Netherlands

Remco has a Bachelor degree in Business Administration (Management, Economics and Law). He has over 20 years of experience in Regulatory Affairs, with a special focus on Global submission procedures, electronic submission and regulatory data management. He has been directly involved in the development and roll-out of the EU Telematics environ¬ment and has in-depth knowledge of the systems. Key areas of expertise include Regula¬tory submissions (new MAA to variations), Global eCTD submission, Regulatory Information Management systems (RIM), xEVMPD, ISO IDMP.

AT THE END OF THE TRAINING, YOU WILL BE ABLE TO

- Understand the complex EU legislation and requirements and increase your knowledge of the latest developments in order to ensure future compliance

USEFUL INFORMATION

This Online Training in divided in 4 modules:

Module 1 | 19 November 2020 from 2.30 pm to 5.30 pm CET
Module 2 | 27 November 2020 from 9.30 am to 12.00 pm CET
Module 3 | 01 December 2020 from 9.30 am to 12.30 pm CET
Module 4 | 04 December 2020 from 9.30 am to 12.30 pm CET

The fee includes: Access to the Online Course, teaching materials in pdf format provided post-training, organizational office support, certificate of attendance.

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: **€ 1.320,00*** (until 06 November 2020)

Ordinary: **€ 1.490,00***

Freelance – Academy – Public Administration**: **€ 780,00***

* for Italian companies: +22% VAT

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

The fee includes: Access to the online training, teaching materials in pdf format provided post-webinar, organizational office support, certificate of attendance.

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.