Advanced FDA Regulatory Affairs

In-depth review of US Regulatory Affairs environment

Type	Date	Language	Location
Corso online - Limited number	4 and 5 November 2020	English	Online

ABOUT

For anyone interested in developing for and registering products in USA, this online training course will give all the required information about how to set-up your product development and successfully achieve registration with FDA.

PROGRAMME

Module 1

Advanced FDA Communications

a) Current Hot topic

- Impact of covid-19
- Update on the programs FDA is working on: cooperation program with other countries for drug approval Project Orbis

b) Formal meetings with FDA

- Scope of meetings

- Meeting types
- Meeting formats
- Type B meetings
- Meeting Request
- Meeting package
- FDA preliminary responses
- How are meetings conducted

FDA Application type and dossier requirements

a) IND
b) New Drug Application: NDA, Art. 505 (b)(2), BLA
c) US generic products – the ANDA pathway

Module 2

FDA programs for Accelerated Development

Expedited pathways – Go Faster!

a) Go faster! Breakthrough Therapy, Fast track, Accelerated Approval and Priority Review
b) Overview of FDA incentives: vouchers, waivers and designations
c) Hot topics: How FDA managed drug-development during covid-19 outbreak?

Advanced regulatory affairs for Drug Development in the US

Orphan Drug Designation (ODD)

a) US ODD requirements
b) Comparison EU vs. US

DMF registration

WHO SHOULD ATTEND

- Regulatory Affairs Manager, Officer and Specialist
- Quality Manager
- Development Pharmacist
- Pharmacovigilance Manager
- Project Manager

working for pharmaceutical company and CROs whit specific interest in FDA regulation.

Participant experience
Basic regulatory knowledge would be preferred

TEACHING METHODS

Theorical explanation of US regulatory framework for drug development, practical tips and tricks for communications with FDA and examples on how to develop and register your product with FDA, including parallel development to EU.

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.

Bruce Thompson

Principal at Reguliance

Bruce is an independent consultant with over 20 years' experience in the pharmaceutical and biotech industries, possessing practical skills in the details of product development planning, regulatory strategy, and project management. He is Principal of Reguliance, which he founded in 2002. He has previous experience in the pharmaceutical industry as Managing Director, Director of Regulatory Affairs and Acting Director for US Regulatory Affairs for several companies for 10 years. He is member of the American Society of Gene & Cell Therapy (ASGCT), the Licensing Executives Society (LES) and the Regulatory Affairs Professionals Society – RAPS (certified 1994).

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

- Understand communication programs with FDA during development
- Have a clear overview of FDA accelerated programs
- Be able to identify the main differences between EU and US in drug development

USEFUL INFORMATION

Online Training – 2 modules

November 4th, 2020 2:00 pm – 6:00 pm CET

November 5th, 2020 2:00 pm – 6:00 pm CET

After the registration, you will receive all details about the connection.

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: **€ 890,00*** (until 14 October 2020)

Ordinary: **€ 1.100,00***

Freelance – Academy – Public Administration**: **€ 540,00***

* for Italian companies: +22% VAT

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

The fee includes: tuitions, organizational office assistance, teaching materials and attendance certificate that will be sent after the training via e-mail.

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.