7 - 8 June 2018, Barcelona
H10 Cubik - Via Laietana, 4 Barcelona

FDA Open Seminar: All you need to know!

Success for drug development and registration

ASPHALION EXTEDO eRegulatory Affairs REGULIANCE MILESTONES TO MARKETS

"FDA Open Seminar – All you need to know!" will provide a structured introduction to all **important aspects of FDA Regulatory Affairs**, but will also cover current **Hot Topics** as well as **recent changes in the US** and their consequences.

The first day, presented jointly with our **US agent Bruce Thompson of Reguliance**, will cover Food and Drug Administration (FDA) basics and all relevant US regulatory activities. Attendees will obtain a comprehensive vision of **when and how to interact with FDA** during drug development and registration phases. **All application types** and the respective **dossier requirements** will be explained and illustrated by **real-life examples**. As suggested by attendees of our previous Open Seminar, we have included this year a **practical case session on meetings with FDA**.

In addition, we are excited to announce two excellent external speakers: **Marta Zanus of CROS NT** will discuss **ISS and ISE requirements**, unique to FDA and a challenge for many companies. **Paula Muñiz of DynaKin** will speak about the possibilities of **modelling techniques in clinical development.**

Due to several important **eCTD deadlines in 2018**, we will also cover the basics of **FDA electronic submission requirements**.

On the second day, attendees will be able to choose between **two parallel sessions**.

Track 1, presented together with our technology partner EXTEDO will offer an **in-depth FDA eCTD software training** (using eCTDmanager™). This practical workshop on eCTD will be a unique occasion to apply your new knowledge and build (your first) FDA eCTD submission.

Track 2 will be a **practical workshop on FDA drug development**. We will cover the details of important regulatory requirements, such as for **Orphan Drug Designation (ODD)** and **pediatric development**, but we will also speak about **regulatory options for adding maximum value to your development**, such as via expedited pathways and FDA incentives. To further increase the interaction with the attendees, we have included **two additional practical cases:** converting an **IMPD to IND** and **US-EU parallel drug development.**

We are pleased to invite you to join us in **Barcelona** to refresh or to start your **FDA knowledge and expertise!**





Registration fee: 400€
(250€ fee for single day participation)

The fee includes: tuition, teaching materials, lunch break on day 1, organizational assistance, attendance certificate.
Fee is subject to 21% VAT

For detailed agenda and registration:
www.asphalion.com/openseminar
openseminar@asphalion.com

Agenda

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7th June '18

8:30 - 9:00	**Registration and welcome coffee**
9:00- 10:20	**FDA basics and Overview of Regulatory Affairs in US** Systematic introduction to FDA and principle regulatory activities for drug development and registration • **FDA in general; recent political changes and their consequences** • **Outline of US regulation of drugs and biologicals; RA timelines actions, acronyms** • **Comparison of US vs. EU regulatory mechanisms** • **Current Hot Topics** • **Questions** *Bruce Thompson, CEO – Reguliance* *Michael Schaub, Director Munich Office – Asphalion S.L.*
10:20 - 11:00	**FDA regulatory affairs during Drug Development** Overview of all important regulatory topics during product development phases • **US Agent requirements** • **Formal meetings with FDA** • **Questions** *Bruce Thompson, CEO – Reguliance*
11:00 - 11:30	**Coffee Break**
11:30 - 12:00	**Practical Case: pre-IND meetings with FDA** When and how to approach the agency • **Practical case: preparing meetings with FDA** • **Questions** *Bruce Thompson, CEO – Reguliance* *Lidia Cánovas, General Manager Regulatory Affairs – Asphalion S.L.*
12:00 - 13:00	**FDA application types and dossier requirements** Introduction to all important application types and respective dossiers: • **IND** • **New Drug Applications: NDA, Art. 505(b)(2), BLA** *Bruce Thompson, CEO – Reguliance* *Michael Schaub, Director Munich Office – Asphalion S.L.*
13:00 - 14:30	**Lunch**
14:30 - 15:15	**Continuation of Session 5** • **US generic products – the ANDA pathway** • **Questions** *Lidia Cánovas, General Manager Regulatory Affairs – Asphalion S.L.*
15:15 - 16:00	**eSubmission: FDA eCTD requirements** Overview of current and future US eCTD requirements, including analysis of differences between USA and Europe • **FDA eCTD requirements and comparison FDA & EU** • **How to comply with specifications for M1, M5, SPL, STF, etc.** • **Dossier and document requirements** • **Questions** *Vicente Tur, Regulatory Affairs Associate Director – Asphalion S.L.* *Ralf-Peter Berg, Director Training & Education – EXTEDO GmbH*
16:00 - 16:30	**Coffee break**
16:30 - 16:50	**Modelling and simulation in Clinical Development for FDA** • **Possibilities of application** • **Integration of modelling into clinical development** *Paula Muñiz, Senior Associate, Consultant – DynaKin, S.L.*
16:50 - 17:10	**Integrated Summaries of Safety and Efficacy (ISS/ISE)** Tips for meeting statistics and data management challenges faced by sponsors • **What to consider when planning the ISS/ISE strategy and when to start planning** • **Identifying and managing the risks related to ISS/ISE** • **What to cover with your ISS/ISE team** *Marta Zanus, Director of Project Management – CROS NT*
17:10 - 17:25	**Post-approval activities** Short introduction into the maintenance of FDA authorized products: • **Post Approval Changes, Annual Reports, and Comparability Protocols** *Lidia Cánovas, General Manager Regulatory Affairs – Asphalion S.L.*
17:25 - 17:45	**Q&A Session – Summary of Day 1**

Meet the speakers:
Reguliance and Asphalion experts will be available for personal meetings on the days before and after the event. You can arrange your meeting at: **fda @asphalion.com**

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8th June '18

8:30 - 9:00	Welcome coffee	**TRACK 1**
9:00- 9:30	**Introduction, starting eCTDmanager, a quick orientation in the application** *Ralf-Peter Berg, Director Training & Education - EXTEDO GmbH*	
9:30 - 10:15	**Workshop 1: Creating an NDA submission with the new FDA Module 1 DTD 3.3.** • See changes compared to DTD 2.01 • Envelope: Application Info / Application Set sections • How to work with forms • How to add an SPL *Ralf-Peter Berg, Director Training & Education - EXTEDO GmbH*	
10:15 - 10:45	Coffee Break	
10:45 - 11:30	**Workshop 2: Study Tagging Files: how to handle CSR, ICH E3 appendices and datasets on your submission** • Study Tagging Files - Automatic STF creation • Adding files to the study • The STF file tags view *Ralf-Peter Berg, Director Training & Education - EXTEDO GmbH*	
11:30 - 12:30	**Workshop 3: exporting and validating the FDA submission** • Exporting "unmodified" files • Using the incremental export option • STF Lifecycle • A quick overview on other US specific features (demo): • Cross Application Linking • Automated Regulatory Activities *Ralf-Peter Berg, Director Training & Education - EXTEDO GmbH*	
12:30 - 13:00	Q&A Session – Summary of Day 1	

8:30 - 9:00	Welcome coffee	**TRACK 2**
9:00- 9:40	**Orphan Drug Designation (ODD)** • US ODD requirements • Comparison EU vs. USA • Questions *Lidia Cánovas, General Manager Regulatory Affairs – Asphalion S.L.*	
9:40 - 10:20	**Pediatric Product Development** • Introduction to all important application types and respective dossiers • US legislation • BPCA and PREA: requirements, incentives, procedures and timelines • Comparison EU vs. US • Questions *Christopher Mann, Scientific & Regulatory Affairs Manager – Asphalion S.L*	
10:20 - 10:50	Coffee Break	
10:50 - 11:30	**Practical Case: Preparation of IND** **... based on an existing European IMPD. "It's easy, right?"** • Differences EU vs. US system • Practical case: preparing an IND from EU IMPD • Questions *Marta Rayo, Scientific & Regulatory Affairs Associate Director – Asphalion S.L.* *Michael Schaub, Director Munich Office – Asphalion S.L.*	
11:30 - 12:15	**Expedited pathways – Go Faster!** **Comprehensive overview of alternative pathways that speed up registration** • Go faster! Breakthrough Therapy, Fast Track, Accelerated Approval, and Priority Review • Overview of FDA incentives: Vouchers, Waivers and Designations • Questions *Marta Rayo, Scientific & Regulatory Affairs Associate Director – Asphalion S.L.* *Lidia Cánovas, General Manager Regulatory Affairs – Asphalion S.L.*	
12:15 - 13:00	**Parallel development in EU and US** **… from the perspective of EU biotech companies** • Strategic considerations before initiating EU-US parallel development • Practical case: EU company developing in US *Bruce Thompson, CEO – Reguliance* *Lidia Cánovas, General Manager Regulatory Affairs – Asphalion S.L.*	
13:00 - 13:30	Q&A Session – Summary of Day 1	