

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

“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

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Agenda

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7th June '18

In collaboration with:

DynaKin

CROS NT

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 <ul style="list-style-type: none">• 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 <i>Bruce Thompson, CEO – Regulance</i> <i>Michael Schaub, Director Munich Office – Asphalion S.L.</i>
10:20 - 11:00	FDA regulatory affairs during Drug Development Overview of all important regulatory topics during product development phases <ul style="list-style-type: none">• US Agent requirements• Formal meetings with FDA• Questions <i>Bruce Thompson, CEO – Regulance</i>
11:00 - 11:30	Coffee Break
11:30 - 12:00	Practical Case: pre-IND meetings with FDA When and how to approach the agency <ul style="list-style-type: none">• Practical case: preparing meetings with FDA• Questions <i>Bruce Thompson, CEO – Regulance</i> <i>Lidia Cánovas, General Manager Regulatory Affairs – Asphalion S.L.</i>
12:00 - 13:00	FDA application types and dossier requirements Introduction to all important application types and respective dossiers: <ul style="list-style-type: none">• IND• New Drug Applications: NDA, Art. 505(b)(2), BLA <i>Bruce Thompson, CEO – Regulance</i> <i>Michael Schaub, Director Munich Office – Asphalion S.L.</i>
13:00 - 14:30	Lunch
14:30 - 15:15	Continuation of Session 5 <ul style="list-style-type: none">• US generic products – the ANDA pathway• Questions <i>Lidia Cánovas, General Manager Regulatory Affairs – Asphalion S.L.</i>
15:15 - 16:00	eSubmission: FDA eCTD requirements Overview of current and future US eCTD requirements, including analysis of differences between USA and Europe <ul style="list-style-type: none">• FDA eCTD requirements and comparison FDA & EU• How to comply with specifications for M1, M5, SPL, STF, etc.• Dossier and document requirements• Questions <i>Vicente Tur, Regulatory Affairs Associate Director – Asphalion S.L.</i> <i>Ralf-Peter Berg, Director Training & Education – EXTEDO GmbH</i>
16:00 - 16:30	Coffee break
16:30 - 16:50	Modelling and Simulation within Clinical Development for FDA <ul style="list-style-type: none">a) Pharmacometrics at FDAb) Example of M&S optimized development <i>Paula Muñoz, Senior Associate, Consultant – DynaKin, S.L.</i>
16:50 - 17:10	Integrated Summaries of Safety and Efficacy (ISS/ISE) Tips for meeting statistics and data management challenges faced by sponsors <ul style="list-style-type: none">• 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 <i>Marta Zanus, Director of Project Management – CROS NT</i>
17:10 - 17:25	Post-approval activities Short introduction into the maintenance of FDA authorized products: <ul style="list-style-type: none">• Post Approval Changes, Annual Reports, and Comparability Protocols <i>Lidia Cánovas, General Manager Regulatory Affairs – Asphalion S.L.</i>
17:25 - 17:45	Q&A Session – Summary of Day 1



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8th June '18

Meet the speakers:

Reguliance and Asphaltion experts will be available for personal meetings on the days before and after the event. You can arrange your meeting at: fd@asphaltion.com

8:30 - 9:00	Welcome coffee	TRACK 1
9:00- 9:30	Introduction, starting eCTDmanager, a quick orientation in the application <i>Ralf-Peter Berg, Director Training & Education - EXTEDO GmbH</i>	
9:30 - 10:15	Workshop 1: Creating an NDA submission with the new FDA Module 1 DTD 3.3. <ul style="list-style-type: none">• See changes compared to DTD 2.01• Envelope: Application Info / Application Set sections• How to work with forms• How to add an SPL <i>Ralf-Peter Berg, Director Training & Education - EXTEDO GmbH</i>	
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 <ul style="list-style-type: none">• Study Tagging Files - Automatic STF creation• Adding files to the study• The STF file tags view <i>Ralf-Peter Berg, Director Training & Education - EXTEDO GmbH</i>	
11:30 - 12:30	Workshop 3: exporting and validating the FDA submission <ul style="list-style-type: none">• 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 <i>Ralf-Peter Berg, Director Training & Education - EXTEDO GmbH</i>	
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) <ul style="list-style-type: none">• US ODD requirements• Comparison EU vs. USA• Questions <i>Lidia Cánovas, General Manager Regulatory Affairs – Asphaltion S.L.</i>	
9:40 - 10:20	Pediatric Product Development <ul style="list-style-type: none">• Introduction to all important application types and respective dossiers• US legislation• BPCA and PREA: requirements, incentives, procedures and timelines• Comparison EU vs. US• Questions <i>Christopher Mann, Scientific & Regulatory Affairs Manager – Asphaltion S.L.</i>	
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?” <ul style="list-style-type: none">• Differences EU vs. US system• Practical case: preparing an IND from EU IMPD• Questions <i>Marta Rayo, Scientific & Regulatory Affairs Associate Director – Asphaltion S.L.</i> <i>Michael Schaub, Director Munich Office – Asphaltion S.L.</i>	
11:30 - 12:15	Expedited pathways – Go Faster! Comprehensive overview of alternative pathways that speed up registration <ul style="list-style-type: none">• Go faster! Breakthrough Therapy, Fast Track, Accelerated Approval, and Priority Review• Overview of FDA incentives: Vouchers, Waivers and Designations• Questions <i>Marta Rayo, Scientific & Regulatory Affairs Associate Director – Asphaltion S.L.</i> <i>Lidia Cánovas, General Manager Regulatory Affairs – Asphaltion S.L.</i>	
12:15 - 13:00	Parallel development in EU and US ... from the perspective of EU biotech companies <ul style="list-style-type: none">• Strategic considerations before initiating EU-US parallel development• Practical case: EU company developing in US <i>Bruce Thompson, CEO – Reguliance</i> <i>Lidia Cánovas, General Manager Regulatory Affairs – Asphaltion S.L.</i>	
13:00 - 13:30	Q&A Session – Summary of Day 1	