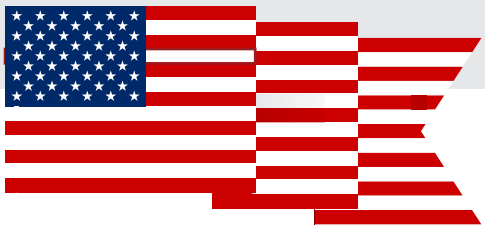
FDA Regulatory Affairs during Drug Development

23 January 2018, Munich (Germany)



BioM Biotech Cluster Development GmbH
Am Klopferspitz 19 a (IZB West II BioM Conference Room, 3. floor)
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It is vital in modern drug development to understand the regulatory requirements and opportunities of the main markets around the world. The US in particular, with its Food and Drug Administration (FDA) leading the way in many aspects of how drugs and biologicals are regulated, needs to be considered in early phases of drug development.

Reguliance and Asphalion invite you to a **practical workshop** that offers an **in-depth look into US FDA Regulatory Affairs,** focusing on **real-life situations of European drug development companies.**
Latest political changes in the US and their practical implications will be discussed as part of the general overview of how FDA operates and what rules apply for the development of human medicines.

All relevant regulatory activities will be explained throughout the sessions and **illustrated by practical cases from the experiences of the speakers**. Topics include FDA meetings, IND strategy for clinical trials, Orphan Drug Designation and Pediatric Product Development.

A central theme of this event will be the analysis of **regulatory options for adding maximum value to your product development.** The best position before partnering/licensing is to consolidate a thorough regulatory strategy in combination with an understanding of FDA incentive and alternative pathways, such as Breakthrough Therapy, Fast Track, Accelerated Approval, and Priority Review. Your speakers will be Bruce Thompson of Reguliance, with 25 years of FDA experience, together with Asphalion's FDA expert team.

Speakers
Bruce Thompson – Principal and Consultant at REGULIANCE
Lidia Cánovas – General Manager Regulatory Affairs at ASPHALION
Christopher Mann – Scientific and Regulatory Affairs Manager at ASPHALION
Michael Schaub – Director Munich Office at ASPHALION

For online registration
please go to **http://bit.ly/2hQiTEy**

Fees
General Public / Industry: 140 €
Student / Academic: 85 €

Agenda

FDA Regulatory Affairs during Drug Development

Time	Nr	Session
08:30 – 09:00		*Registration and welcome coffee*
09:00 – 09:10	**1.**	*Introductions*
09:10 – 09:50	**2.**	*US FDA basics* Systematic introduction to US Regulatory Affairs **a) FDA in general; recent political changes and their consequences** **b) Outline of US regulation of drugs and biologicals** **c) Comparison of US vs. EU regulatory mechanisms**
09:50 – 10:20	**3.**	*Overview of FDA regulatory affairs during development* **a) Global timelines, mandatory vs. optional actions, comparison with EU, acronyms** **b) Current Hot Topics**
10:20-10:40		*Coffee break*
10:40 – 11:30	**4.**	*Interactions with FDA* When and how to approach the agency **a) Pre-IND meetings** **b) US Agent requirements** **c) *Practical case:* preparing meetings with FDA**
11:30 – 12:10	**5.**	*FDA Investigational New Drug – IND* Detailed presentation of IND requirements **a) Background and definition** **b) Structure and content** **c) Submission and User Fees** **d) IND maintenance** **e) Differences EU vs. US system** **f) *Practical case:* preparing an IND from EU IMPD ("It's easy, right?")**
12:10 – 13:10		*Lunch break*
13:10 – 13:30	**5.**	*Continuation of Session 5*
13:30 – 13:55	**6.**	*Orphan Drug Designation (ODD)* Incentives and requirements for rare disease products **a) US ODD requirements** **b) Comparison EU vs. USA**
13:55 – 14:25	**7.**	*Pediatric Product Development* Introduction to all important application types and respective dossiers **a) US legislation** **b) BPCA and PREA: requirements, incentives, procedures and timelines** **c) Comparison EU vs. US**
14:25 – 15:10	**8.**	*Analysis of regulatory options from early development until licensing-out* Using your development strategy for adding maximum value before selling or partnering **a) Regulatory milestones prior to licensing** **b) *Go faster!* Breakthrough Therapy, Fast Track, Accelerated Approval, and Priority Review** **c) Overview of FDA incentives: Vouchers, Waivers and Designations**
15:10 – 15:40		*Coffee Break*
15:40 – 16:10	**9.**	*Parallel development in EU and US: further details* … from the perspective of EU biotech companies **a) Strategic considerations before initiating EU-US parallel development** **b) *Practical case:* EU company developing in US**
16:10 – 16:30	**10.**	*Q&A Session*

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