Asphalion Open Doors

Latest Insights on EU and US Scientific & Regulatory Affairs

7th June 2019 · H10 Itaca - Barcelona

Organised by:

ASPHALION

In collaboration with:

REGULIANCE

EXTEDO eRegulatory Affairs

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Agenda

Latest Insights on Scientific & Regulatory Affairs

7th June ‘19

TRACK 1

9:30 - 10:00	**Registration and welcome coffee**
10:00- 10:45	**Latest EU and US Regulatory and Scientific News & Statistics** Update on related Services and introduction of Asphalion partners *Remco Munnik, Regulatory Information Director – Asphalion S.L.*
10:45 - 11:30	**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 *Bruce Thompson, CEO – Reguliance* *Michael Schaub, Director Munich Office – Asphalion S.L.*
11:30 - 12:00	**Coffee Break**
12:00 - 12:45	**Tools for faster access to medicines – How to make use of existing tools and incentives to expedite development and registration:** • Innovation Task Force • Scientific Advice • PRIME scheme (PRIority MEdicines) • Conditional approval • Interact Meetings • Type B meetings • Breakthrough therapy Introduction of the available tools to expedite the registration process for innovative or repurposed medicinal products. Overview of the designation and pathways for FDA and EMA. *Marta Rayo Lunar, Scientific & Regulatory Affairs Associate Director – Asphalion S.L.*
13:00 - 15:00	**Lunch**
15:00 - 15:45	**How to survive Quality-by-Design (QbD) requirements?** A practical approach on how to implement a QbD pharmaceutical development. • *Regulatory Framework* • *QbD Fundamentals – QTTP, CQA, MQA, CPP, Control Strategy* • *Types of QbD – how far should I go?* • *When and how to implement?* • *Useful tips and some common issues* *André Mota, Madrid Office Director – Asphalion S.L.*
15:45	**Coffee break & networking at Asphalion Offices**
16:00	**Demos**
16:00 - 17:00	**Demos at Asphalion offices of:** • Safety Easy PV (Ab Cube - EXTEDO) • RIManager (EXTEDO) • eCTD Manager (EXTEDO) *Remco Munnik, Regulatory Information Director – Asphalion S.L.* *Núria Cabello, Senior Drug Safety Officer - Asphalion S.L.*

TRACK 2

9:30 - 10:00	**Registration and welcome coffee**
10:00- 10:45	**Challenges of the new Medical Device Regulation: Latest News** Update on related Services and introduction of Asphalion partners • Extension of scope according to technological progress • Changes in classification: new rules and systems • Focus on risk/benefit profile • Forthcoming implementations: UDI & EUDAMED *Lidia Cánovas, General Manager Regulatory Affairs – Asphalion S.L.* *Dominique Monferrer, Scientific & Regulatory Affairs Associate Director – Asphalion S.L.*
10:45 - 11:30	**Digital media, a challenge in Pharmacovigilance?** • Digitalization • Legislation • Keys to move from a manual process to an automatic process (active listening) • Analysis and validation of cases found on the internet • Case study *Sonia López, Qualified Person Responsible for Pharmacovigilance - Asphalion S.L.* *Núria Cabello, Senior Drug Safety Officer - Asphalion S.L.* *David Martí, Director - Playbrand, S.L.*
11:30 - 12:00	**Coffee Break**
12:00 - 12:45	**Global status of electronic submission** • Global overview of the use and implementation of eCTD • Move from documents to structured data *Vicente Tur, Regulatory Affairs Associate Director – Asphalion S.L.* *Remco Munnik, Regulatory Information Director – Asphalion S.L.*
13:00 - 15:00	**Lunch**
15:00 - 15:45	**IDMP and the impact of Regulatory Affairs** A practical approach on how to implement a QbD pharmaceutical development. • ISO IDMP, compliance or opportunity? • Status of implementation in EU • Getting prepared for IDMP *Remco Munnik, Regulatory Information Director – Asphalion S.L.* *Marcos Fernandez, Regulatory Affairs Manager – Asphalion S.L.*
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Meet the speakers:
All collaborators and Asphalion experts will be available for personal meetings on the days before and after the event. You can arrange your meeting at: **openseminar @asphalion.com**

More information and free registration here: https://bit.ly/2UDUyEk