Thursday, 16 May 2019

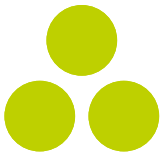
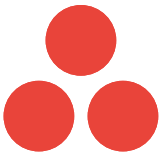
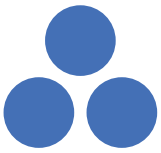
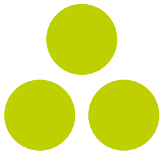
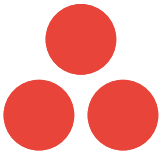
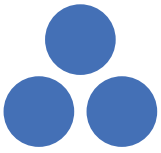
9:00	**Welcome and Introduction**	Falk Klar, *PDA Europe* Susanne Keitel, *PhD, EDQM, Conference Chair* Nadine Ritter, *Global Biotech Experts, Conference Co-Chair*
Session 1: Working Principles of Pharmacopoeias in Their Regulatory Framework		*Moderators:* **Nadine Ritter,** *Global Biotech Experts* **Janeen Skutnik-Wilkinson,** *Biogen*
9:10	**The European Pharmacopoeia: A Successful Example of How a Pharmacopoeia Supports and Fosters Implementation of Regulatory Texts**	Susanne Keitel, *European Directorate for the Quality of Medicines & HealthCare (EDQM)*
9:40	**Ensuring Quality of Medicines: Role of USP Standards**	Jaap Venema, *United States Pharmacopoeia (USP)*
10:10	**Japanese Pharmacopoeia**	Tsuyoshi Ando, *Pharmaceuticals and Medical Devices Agency (PMDA)*
10:40	**Coffee Break, Poster Session & Exhibition**	
11:10	**Brazilian Pharmacopoeia: Working Principles and Regulatory Framework**	Riviane Matos Gonçalves, *Brazilian Health Regulatory Agency (ANVISA)*
11:40	**Place and Role of the Indian Pharmacopoeia Commission in Promoting Quality and Safety of Medicines**	Manisha Trivedi, *Indian Pharmacopoeia Commission (IPC)*
12:10	**WHO Updates: International Perspective**	Sabine Kopp, *World Health Organization (WHO)*
12:40	**Q&A, Panel Discussion with International Representatives**	
13:15	**Lunch Break, Poster Session & Exhibition**	
Session 2: Introduction to Breakout Session		*Moderator:* **Susanne Keitel, EDQM**

The three presentations of this introductory session will highlight recent developments and current hot topics for each of the breakout sessions to set the scene and stimulate discussion.

14:15	**Analytical QbD and the Pharmacopoeia**	James Pound, *Medicines and Healthcare Products Regulatory Agency (MHRA)* Graham Cook, *Pfizer*
14:45	**Evolution of the Compendial Landscape – Product Specific Monographs for Biotherapeutics**	Mihaela Buda, *EDQM* Joseph A. Albanese, *Janssen, J&J*
15:15	**Continuous Manufacture of Drug Products and Drug Substances**	Andrew Rutter, *GSK* Graham Cook, *Pfizer on behalf of European Federation of Pharmaceutical Industries and Associations (EFPIA)*
15:45	**Coffee Break, Poster Session & Exhibition**	

16:15	Breakout Sessions – Roundtable Discussions

Attendees will choose two of the three topics offered and engage in discussions with the experts for 45 minutes each. A brief summary of the main questions and conclusions drawn after hearing the various perspectives will be presented to the entire audience before we close out this first day.

	ANALYTICS	BIOTHERAPEUTICS	MANUFACTURING
	Moderators: James Pound, *MHRA* Vinny Browning, *Amgen*	Moderators: Nadine Ritter, *Global Biotech Experts* Mihaela Buda, *EDQM*	Moderators: Graham Cook, *Pfizer* Cathie Vielle, *EDQM*
16:15			
17:00			

17:45	**Brief Summary of Highlights from the Roundtable Discussions**
18:00	**End of Day 1 & Networking Event in Geneva**

2019 PDA Europe

Pharmacopoeia Committee and Speaker Biographies

and many more....find them all online!

https://t1p.de/jfah

THE PDA IS PROUD TO INVITE YOU TO A VERY SPECIAL NETWORKING EVENT.

Join us for a fabulous evening in the heart of Geneva at Brasserie Halles de l'île.

Located on an island in the Rhône river close to the lake, it's famous for their tapas and the outdoor terraces with a view of the river, the city and the mountains.

16 May 2019

18:30h – Meeting Point: Hotel Lobby. Joint short walk and tram trip
19:00h – Dinner, Brasserie Halles de l'île, Place de l'île 1, 1204 Geneva
21:00h – Return via tram to Conference Hotel

Friday, 17 May 2019

PARALLEL TRACKS

Session 3	TRACK A REFERENCE STANDARDS – MANUFACTURE AND CHARACTERIZATION	TRACK B PRACTICAL EXAMPLES OF MONITORING, ASSESSMENT AND IMPLEMENTATION OF PHARMACOPOEIAL CHANGES
	Moderator: **Vinny Browning,** *Amgen*	Moderator: **Frithjof Holtz,** *Merck*
	In this section of the meeting, we will focus on reference standards. We will explore the use of compendial reference standards for validation purposes, review the latest developments from the USP as it relates to Biological reference standards, discuss Bioassay international reference standards, and hear about compendial equivalence for in-house reference standards.	The manufacture and supply of many medicines involves global supply chains and therefore an understanding of, and compliance with, multiple pharmacopoeial requirements. This session will provide an opportunity to learn about the approaches used in companies to manage this diversity and discuss best practices for compliance.
9:00	**Use of Compendial Reference Standards for Instrument Qualification and Method Validation** Stefan Almeling, *EDQM*	**Case Study: A Process for Monitoring and Engaging with Pharmacopoeias** Janeen Skutnik Wilkinson, *Biogen*
9:30	**Latest Developments in USP Biologics Performance Standards** Kevin Carrick, *USP*	**Compendial Compliance in a Global Environment: Process Optimization for Pharmacopoeia Review** J. Mark Wiggins, *Global Pharmacopoeia Solutions*
10:00	**Coffee Break, Poster Session & Exhibition**	
10:30	**Bioassay International Standards for Monoclonal Antibodies: New Reagents for New Challenges** Sandra Prior, *National Institute for Biological Standards and Control (NIBSC)*	**Case Study of Particulate Matter in Biopharmaceutical Drug Products – Leveraging Working Groups and White Papers** Jan Stracke, *F. Hoffmann-La Roche*
11:00	**Compendial Equivalence of In-house Reference Standards - Learnings and Key Challenges of the Process** Aoife Mee, *Novartis*	**Panel Discussion, Q&A**
11:30	**Q&A, Discussion**	
12:00	**Lunch Break, Poster Session & Exhibition**	

Session 4: Process for Prioritization in Convergence of Monographs and Maintenance of Convergent Status		*Moderator:* **Paolo Tozzi,** *Novartis*
This session will include a presentation discussing how a global company manages pharmacopoeial changes and provide some perspectives relating to international harmonization and convergence of pharmacopoeial standards.		
13:00	**An Effective Process for Monitoring, Assessing, and Implementing Compendial Changes at a Global Pharmaceutical Company**	Matthew Borer, *Eli Lilly*
13:30	**An Industry Perspective on the Need for Harmonization / Convergence of Public Standard Activities**	Philip Travis, *Pfizer on behalf of EFPIA*
14:00	**Update on Recent PDG Developments and the New Maintenance Procedure on the ICH Q4B Annexes Adopted by the ICH Assembly**	Cathie Vielle, *EDQM*
14:30	**Q&A, Panel Discussion**	
15:00	**Coffee Break, Poster Session & Exhibition**	
15:30	**Closing Keynote – Joint Reflection from Pharmacopoeia & Industry**	Susanne Keitel, *EDQM* Graham Cook, *Pfizer*
16:00	**Closing Remarks**	Susanne Keitel, *EDQM* Nadine Ritter, *Global Biotech Experts* Falk Klar, *PDA Europe*
16:30	**End of Conference**	