13 Dec 2018

# Thursday, 16 May 2019

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| **9:00** | **Welcome and Introduction** | Falk Klar, *PhD, PDA Europe*<br>Susanne Keitel, *PhD, EDQM, Conference Chair*<br>Nadine Ritter, *PhD, Global Biotech Experts, Conference Co-Chair* |

## Session 1: Working Principles of Pharmacopoeias in Their Regulatory Framework

In this opening session, invited international representatives will share specifics with respect to their agencies'

- Legal Status
- Governing Bodies
- Decision-making
- Methods & Tech Transfer: Minimum Requirements from a Pharmacopoeial Perspective
- Acceptance of Alternative Methods / Definition of Alternative Methods

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| | **European Pharmacopoeia** |
| | **Unites States Pharmacopoeia** |
| | **Japanese Pharmacopoeia** |
| **10:45** | **Coffee Break, Poster Session & Exhibition** |
| | **Chinese Pharmacopoeia** |
| | **Russian Pharmacopoeia** |
| | **Brazilian Pharmacopoeia** |
| | **Indian Pharmacopoeia** |
| **13:00** | **Lunch Break, Poster Session & Exhibition** |

## Session 2: Breakout & Roundtables

**14:00** **Introduction of Topics & Format**
Participants will get to choose two out of three topics. You will have the opportunity to share experiences and pose questions in each roundtable for 45 minutes.

| ANALYTICS | BIOTHERAPEUTICS | MANUFACTURING |
|---|---|---|
| Validation of Ph Methods Acceptance Criteria, Change Management, Established Conditions, ICH Q12, Inter-changeability of Analytical Methods, QbD, etc. | ATMPs, Monoclonal Antibodies, Biosimilars / Biobetters, etc. | Continuous Manufacturing, PAT, Control of Impurities, etc. |

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| **15:30** | **Coffee Break, Poster Session & Exhibition** |
| | **Summary of Roundtable Discussions** |
| | **Industry Perspective*** |
| | **Industry Perspective*** |
| **18:00** | **End of Day 1 & Networking Reception** |

## Friday, 17 May 2019

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| **9:00** | **Summary of Day 1:**<br>**Take-Aways, Learnings from Regulatory and Industry Perspectives** | |
| | **PARALLEL TRACKS** | |
| | **TRACK A**<br><br>**REFERENCE STANDARDS – MANUFACTURE AND CHARACTERIZATION** | **TRACK B**<br><br>**PRACTICAL EXAMPLES OF MONITORING, ASSESSMENT AND IMPLEMENTATION OF PHARMACOPOEIAL CHANGES** |
| **9:30** | **EDQM** | **Case Study:**<br>**A Process for Monitoring and Engaging with Pharmacopoeias** |
| **9:30** | **USP** | **Industry Perspective*** |
| **10:30** | **Coffee Break, Poster Session & Exhibition** | |
| | **National Institute for Biological Standards and Control / British Pharmacopoeia** | **Industry Perspective*** |
| | **WHO,** *invited* | **Industry Perspective*** |
| **12:30** | **Lunch Break, Poster Session & Exhibition** | |
| **Session 4: Process for Prioritization in Convergence of Monographs and Maintenance of Convergent Status** | | |
| **13:30** | **Update on Recent PDG Developments:**<br>**New Maintenance Procedure on the ICH Q4B Annexes** | |
| | **Industry Perspective*** | |
| **15:00** | **Coffee Break, Poster Session & Exhibition** | |
| | **Bilateral Working Principles: Harmonization Efforts** | |
| | **Closing Keynote – Future Perspectives & Outlook** | |
| | **Closing Panel, Q&A, Discussion** | |
| **16:30** | **Summary & End of Conference** | |

Draft Program, all details subject to change without prior notice.

*PDA is still seeking abstract proposals for available speaking slots! **SUBMIT TODAY!**