20 June 2019

Tuesday, 3 September 2019

9:00	**Welcome: Opening Remarks & Introductions**	Kerstin Wilken, *PDA Europe* Cristiana Campa, *Chair, GSK Vaccines* Michael De Felippis, *Chair,* Eli Lilly
Opening Plenary: Updates in Biomanufacturing		*Moderator:* **Cristiana Campa,** *GSK Vaccines*
	Reinventing Biopharma Through Digital and Analytics	Alvaro Carpintero, *McKinsey & Company*
	Regulatory Perspectives on Accelerated Access and a Summary of the EMA/FDA 2018 Workshop on Support to Quality Development in Early Access Approaches	Mats Welin, Medical Products Agency Sweden European Medicines Agency, speaker invited
	Q&A, Discussion	
11:00	**Coffee Break, Poster Session & Exhibition**	

TRANSITION TO PARALLEL TRACKS

Session 1	**Track A**	**Track B**
Topic	**Accelerated Access**	**Considerations on Facility Design**
Moderator:	Martijn van der Plas, *Dutch Medicines Evaluation Board*	Elisabeth Vachette, *Sartorius Stedim*
11:30	**Challenges for Registration and Opportunities to Increase Alignment of Requirements in Emerging Countries** MSD	**The Right Facility Setup Considerations** NNE
	CMC Criteria for Accelerated Access of Vaccines GSK Vaccines	**Engineering and Facility Design Challenges in Novel Therapeutic Vaccines and New Generation Biologics** DPS Group
	Q&A, Discussion	**Case Study: Introduction of a New Highly Potent Biopharmaceutical Product into an Existing Facility** Minapharm
		Q&A, Discussion
13:00	**Lunch Break, Poster Session & Exhibition**	

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TRANSITION TO THREE PARALLEL TRACKS			
Session 2	**Track A**	**Track B**	**Track C**
Topic	**ICH Q12 Guideline**	**New Modalities & Novel Vaccines**	**Approaches to Microbial Control and Sterilization Methods**
Moderator:	Florence Wauters, *MSD*	Susanne Joerg, *LONZA*	Walid El-Azab, *STERIS*
14:00	**An Update on ICH Q12** Nanna Kruse, *Danish Medicines Agency*	**Challenges in the Development of Biologics - A Regulator's Perspective** Austrian Agency for Health and Food Safety	**Advancing QC Microbiology Modernization Through Cross-industry Collaboration** GSK
	ICH Q12 Implementation from an Industry Perspective with a Focus on Established Conditions GSK Vaccines	**The Manufacture of New Modalities** LONZA	**How to make the Optimal Choice for the Final Sterilization of Pharmaceutical Products** Sterigenics
	Post Approval Changes in Biologics Manufacturing - a Practical Assessment from a Supplier's Perspective Merck KGaA	**Fighting Pathogens and Toxins with Human and Human-like Recombinant Antibodies** Technical University Braunschweig	Speaker, *invited*
	Q&A, Discussion	**Q&A, Discussion**	**Q&A, Discussion**
15:45	**Coffee Break, Poster Session & Exhibition**		
Session 3	**Track A**	**Track B**	**Track C**
Topic	**Continuous Manufacturing and ICH Q13**	**From the Drug Substance to the Finished Product**	**Automation & Digitalization**
Moderator:	Florence Wauters, *MSD*	Susanne Joerg, *LONZA*	Falk Klar, *PDA Europe*
16:15	**ICH Q13 Continuous Manufacturing of Drug Substances and Drug Products – Where Are We with This Guidance?** MSD	**The "Fate of Leachables" in Biopharmaceutical Downstream Processes** Sartorius Stedim	**Digital Twin of a Vaccine Process** GSK Vaccines

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	Continuous Manufacturing of MAbs US FDA	**Degradation of Excipients in Formulations** LONZA	**Presentations around topics such as** • Novel technologies to digitalize the interface between patients and the drug product • Automation and digitalization of the manufacturing process • Big Data and Data Management
	Continuous Downstream Processing: Comparability and Regulatory Risks Bayer	 Speaker, *invited*	
	Q&A, Discussion	**Q&A, Discussion**	**Q&A, Discussion**
18:00	**End of Day 1 & Networking Event**		

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NETWORKING RECEPTION

The Parenteral Drug Association is proud to invite you to a special Networking Reception. Join us at the conference venue and enjoy an evening of exchange with peers and colleagues!

Tuesday, 3 September 2019
18:30 - 21:30

Wednesday, 4 September 2019

PARALLEL TRACKS

Session 4	Track A	Track B	Breakout Session
Topic	**Considerations for ICH Q2/Q14 and Advancements in Test Methodologies**	**Quality by Design Enabled Control Strategies**	**Interest Group Meeting Filtration** - open to all -
Moderator:	Félix Montero-Julian, *BioMérieux*	Michael De Felippis, *Eli Lilly*	Sebastian Teitz, *Asahi Kasei* Michiel Rook, *Global Consept*
9:00	**A Regulatory Perspective on Alternative Test Methods** European Directorate for the Quality of Medicines & HealthCare	**Engineering-Driven Application of Quality by Design to the GMMA Platform: Enabling the Production of Affordable and Effective Vaccines for Low- and Middle-Income Countries** Imperial College London	**Take advantage of the open forum design offered by this focused Interest Group meeting. Hear presentations from leading experts and interact and discuss your experiences with colleagues in a familiar atmosphere.** **Share your opinion and enlarge your knowledge interactive discussion rounds. Receive the latest information about activities of the Interest Group Filtration and Virus Safety.** **Alternative Approaches to Segregation in Facility Design and Operation** *MSD* **Passage of Soft Pathogens Through Microfiltration Membranes Scales with Transmembrane Pressure** *Sartorius Stedim*
	Revision of ICH Q2(R1) and new ICH Q14 guidance - Opportunities for The Life Cycle Management of Analytical Procedures F. Hoffmann - La Roche	**Phase Appropriate and Risk-based Design of a Bioburden and Sterilization Control Strategy for New Vaccines Candidates** GSK Vaccines	
	Replacing in Vivo Potency Test With In Vitro Assay: Challenges and Expectations GSK Vaccine	**Regulatory Perspective on Control Strategies** Martijn van der Plas, *Dutch Medicines Evaluation Board*	
		Q&A, Discussion	
10:30	**Coffee Break, Poster Session & Exhibition**		

PARALLEL TRACKS

Session 5	Track A	Track B	Track C
Topic	**Considerations for ICH Q2/Q14 and Advancements in Test Methodologies (cont'd)**	**Water for Injection: Implementation of the New Guideline**	**Practical Approaches to Contamination Control**
Moderator:	Michael De Felippis, *Eli Lilly*	Kerstin Wilken, *PDA Europe*	Walid El-Azab, *STERIS*

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11:00	**Development of Innovative and More Precise Methods for Replacement of In Vivo Release Tests of Authorized Vaccines in The IMI VAC2VAC Project** Dutch Medicines Evaluation Board	**WFI Using Membrane Technology - First Impressions after the Regulatory Change** Merck KGaA	**Contamination Control Strategy** VTU Engineering
	Applying a Next Generation Sequencing Workflow to Accelerate Biopharmaceutical Manufacturing Processes and Improve Safety Genedata	**Membrane-based ambient WFI for Biomanufacturing: Regulatory Background - Opportunities and Risks** CRB Group	**Are You Wearing Too Little or Too Much: Optimizing Gowning Controls for Reduced Bioburden Manufacturing** MSD
	Q&A, Discussion	**Q&A, Discussion**	**Q&A, Discussion**
12:30	**Lunch Break, Poster Session & Exhibition**		

TRANSITION TO TWO PARALLEL TRACKS

Session 7	**Track A**	**Track B**
Topic	**Single Use Systems**	**Comparability**
Moderator:	Elisabeth Vachette, *Sartorius Stedim*	Cristiana Campa, *GSK Vaccines*
13:30	**Reduction of Risks from Particulate Matter in Single-Use Systems** Sartorius Stedim	**FDA's Totality of Evidence for Risk-Based Comparability Protocols Over Lifecycle and for Similarity Assessments** 4TuneEngineering
	Development of a Scalable Adenovirus-Based Rabies Vaccine Based on Single Use Technologies Merck KGaA	**Comparability Risk Assessment** UCB
	Q&A, Discussion	**Q&A, Discussion**
14:40	**Coffee Break, Poster Session & Exhibition**	

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Closing Plenary: **Panel Discussion with European Regulatory Representatives**		*Moderator:* **Michael De Felippis,** *Eli Lilly*
15:10	**Panel discussion including relevant topics such as** • Introduction to the EMA 2025 Regulatory Science Strategy • Post Approval Changes • Revision of ICH Q2(R1) and new ICH Q14 guidance • PUPSIT • Comparability • Accelerated Access • And More Hot Topics from the Conference	European Medicines Agency, *invited* Nanna Kruse, *Danish Medicines Agency* Mats Welin, *Medical Products Agency Sweden* Martijn van der Plas, *Dutch Medicines Evaluation Board* European Directorate for the Quality of Medicines & HealthCare, *invited* Austrian Agency for Health and Food Safety, *invited*
	Conference Summary & Conclusions	Cristiana Campa, Chair, GSK Vaccines Michael De Felippis, Chair, Eli Lilly
16:30	**Closing Remarks** **End of Conference & Farewell**	Kerstin Wilken, *PDA Europe*

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