PDA BioManufacturing Conference 2025

Agenda

Tuesday, 23 September

CEST Daylight Time (UTC +2:00)

08:00 – 17:30	**Registration Hours**
09:00 – 09:10	**Welcome and Introduction** **Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*
09:10 – 09:20	**Welcome from the Co-Chairs** **Co-Chair: Sabine Hauck Dr**, Consultant, . **Co-Chair: Maria Papathanasiou PhD** Associate Professor (UK Senior Lecturer) *Department of Chemical Engineering, Imperial College London*
09:20 – 11:30	**Opening Plenary: Shaping Regulations for the Future** **Moderator: Maria Papathanasiou PhD**, Associate Professor (UK Senior Lecturer), *Department of Chemical Engineering, Imperial College London* **Moderator: Sabine Hauck Dr** Consultant .

09:20 – 09:45	**Regulatory Update from EMA** • **Regulatory Presenter: Brian Dooley BSc(Pharm), MSc**, Pharmaceutical Quality Senior Specialist , *European Medicines Agency*
09:45 – 10:10	**Europe at the Cutting Edge of Manufacturing Innovation and Competitiveness** • **Presenter: Mónica Perea-Vélez MSc, PhD**, CMC Advocacy and Policy Director, *GSK*
10:10 – 10:35	**Quality Requirements for Radiopharmaceuticals Based on Monoclonal Antibody Derivatives** • **Regulatory Presenter: Steffen Gross PhD**, Head Section Qualtiy and Non-clinical Evaluation of Antibody Therapeutics, *Paul-Ehrlich-Institute*
10:35 – 10:45	**Biomanufacturing Innovations & Regulatory Framework: A PDA Perspective** • **Presenter: Josh Eaton MS**, Senior Director, Scientific and Regulatory Affairs, *PDA*
10:45 – 11:30	**Plenary Discussion** • **Moderator: Maria Papathanasiou PhD**, Associate Professor (UK Senior Lecturer), *Department of Chemical Engineering, Imperial College London* • **Moderator: Sabine Hauck Dr**, Consultant, . • **Regulatory Panelist: Steffen Gross PhD**, Head Section Qualtiy and Non-clinical Evaluation of Antibody Therapeutics, *Paul-Ehrlich-Institute* • **Regulatory Panelist: Brian Dooley BSc(Pharm), MSc**, Pharmaceutical Quality Senior Specialist , *European Medicines Agency* • **Panelist: Mónica Perea-Vélez MSc, PhD**, CMC Advocacy and Policy Director, *GSK*

11:30 – 12:00	**Networking Coffee Break, Poster Session & Exhibition**

Session 1: Tackling Manufacturing Challenges

Moderator: Sebastian Groel PhD, Manager Formulation Technology, *Daiichi Sankyo Europe*

12:00 – 13:15	
12:00 – 12:15	**Leveraging Functional Equivalence of Process Manufacturing Equipment and Materials to Streamline Lifecycle Management of Commercial Biologics Processes** • **Presenter: Cillian McCabe PhD, Fellow of the Royal Society of Chemistry**, Director Technical Services Manufacturing Sciences, *Eli Lilly and Company*
12:15 – 12:30	**Implementation of Annex 1 by Primary Packaging Suppliers: Supplier Case Study Implementation to Improve Particle Control and Reduces Interventions for Improved Compliance** • **Presenter: Colleen O'Brien MS**, Strategy and Technical Affairs, *Gerresheimer*
12:30 – 12:45	**GMP-Ready Continuous Freeze-Drying: Scalable Technology with Case Studies and Data** • **Academic Presenter: Thomas De Beer PhD**, Professor, *Ghent University*
12:45 – 13:15	**Q&A Discussion** • **Moderator: Sebastian Groel PhD**, Manager Formulation Technology, *Daiichi Sankyo Europe* • **Panelist: Cillian McCabe PhD, Fellow of the Royal Society of Chemistry**, Director Technical Services Manufacturing Sciences, *Eli Lilly and Company* • **Panelist: Colleen O'Brien MS**, Strategy and Technical Affairs, *Gerresheimer* • **Academic Panelist: Thomas De Beer PhD**, Professor, *Ghent University*

Guided Poster Walk

Moderator: Orla McCarthy MPharm, Associate Principal Scientist International CMC EU/EEMEA, *Merck Sharp & Dohme*

13:15 – 13:45	**Development of a Simulated Air and Land Bulk Shipment Study Platform to enable the Shipment of High Concentration Pre-filled Syringe (PFS) Drug Product (DP) in a 1.0 mL Syringe Primary Packaging** • **Poster Presenter: Angélica de Lourdes Rodríguez López** , ,
13:15 – 13:45	**SUS Interchangeable Parts: Biopharmaceutical Manufacturers and Single-Use Suppliers Collaboration – BioPhorum Interchangeability Assessment and Qualification Best Practice Guide** • **Poster Presenter: Nicola Powell** , ,
13:15 – 13:45	**Advanced Solutions for Aseptic Material Transfer** • **Poster Presenter: Valentina Ratti MSc enginnering**, Strategic Marketing Manager, *FEDEGARI*
13:15 – 13:45	**In-Line UV Spectrometry Monitoring in Cleaning Validation** • **Poster Presenter: Brian Bosso** , Technical Service Manager, *STERIS Corporation*
13:15 – 13:45	**Strategic Changes to a Legacy Cleaning Approach Result a in More Sustainable Process** • **Poster Presenter: Dijana Hadziselimovic** , ,

13:15 – 13:45	13:15 – 13:45	**Impact of Poloxamer 188 Crystallization on Viral Stability in Lyophilized Formulations** • **Poster Presenter: Angela Valentic** , ,
	13:15 – 13:45	**Application of Single-Use Systems in Biomanufacturing: Contamination Control Strategies For Particulate Matter** • **Poster Presenter: Klaus R. Wormuth PhD**, Principal Scientist, *Sartorius*
	13:15 – 13:45	**PUPSIT Simulation During Process-Specific Bacterial Retention Testing (PUPSIT-BCT)** • **Poster Presenter: Yvonne Groß Dipl.-Ing**, Senior Scientist, *Sartorius Stedim Biotech*
	13:15 – 13:45	**Improving VHP Distribution for Decontamination using Magnetically Levitated Fans** • **Poster Presenter: Ivana Festera** , ,
	13:15 – 13:45	**Trending and Pattern Recognition for Annex 1** • **Poster Presenter: Susan B. Cleary EMBA**, Director Product Development, *Novatek*
	13:15 – 13:45	**Refolution´s Sustainable Freezing Systems** • **Poster Presenter: Thomas Frank Dipl Ing**, CEO, *Refolution Industriekälte GmbH*
	13:15 – 13:45	**The Growth Direct® System:Improving Processes and Quality for Environmental Monitoring for ATMPs** • **Poster Presenter: Ivo Buzzi** , ,
	13:15 – 13:45	**Sartopore® Evo — Embracing A PFAS Free Future in Bio-Pharmaceutical Fill & Finish Operations** • **Poster Presenter: Holger Bromm** , Principal Expert Filtration, *Sartorius Stedim Biotech GmbH*
13:15 – 14:30	**Networking Lunch Break, Poster Session & Exhibition**	
14:30 – 15:55	**Session 2: Novel Analytical Approaches to Elucidate Various Product Attributes** **Moderator: Pepijn Burgers PhD**, Scientific Director Biologics AD , *JnJ Innovative Medicine*	
	14:30 – 14:40	**Interactive Questionnaire Session** • **Moderator: Pepijn Burgers PhD**, Scientific Director Biologics AD , *JnJ Innovative Medicine*
	14:40 – 14:55	**Characterizing Biologics Using wNMR** • **Academic Presenter: Bruce Yu PhD**, Professor, *University of Maryland School of Pharmacy*
	14:55 – 15:10	**Advancing Stability: The Essential Role of Primary Container Selection in Viral Vector Drug Products** • **Presenter: Olga Labovitiadi PhD**, Scientific Associate Director , *JnJ Innovative Medicines Drug product Development and Delivery*
	15:10 – 15:25	**Innovative Tools to Support Particle Identification and Characterization in (Bio)Pharmaceuticals** • **Presenter: Daniel Demminger Dr**, Senior Scientist, *Coriolis Pharma Research GmbH*
		Q&A Discussion

15:25 – 15:55	• **Moderator: Pepijn Burgers PhD**, Scientific Director Biologics AD , *JnJ Innovative Medicine* • **Academic Panelist: Bruce Yu PhD**, Professor, *University of Maryland School of Pharmacy* • **Panelist: Olga Labovitiadi PhD**, Scientific Associate Director , *JnJ Innovative Medicines Drug product Development and Delivery* • **Panelist: Daniel Demminger Dr**, Senior Scientist, *Coriolis Pharma Research GmbH*
15:55 – 16:25	**Networking Coffee Break, Poster Session & Exhibition**
16:25 – 17:55	**Session 3: New Treatment Modalities: Bacteriophages and Virus-Like Particles** **Regulatory Moderator: Veronika Jekerle PhD**, Head of Pharmaceutical Quality, Human Medicines, *European Medicines Agency*
16:25 – 17:45	**Regulatory and Quality Aspects of Phage Therapy Medicinal Products** • **Regulatory Co-Presenter: Helerin Eiche PhD**, Quality Assessor of Biological Medicinal Products, *State Agency of Medicines (Estonia)* • **Regulatory Co-Presenter: Daniel Holý Ing**, Quality Assessor of Biological Medicinal Products, *State Institute for Drug Control (Czechia)*
16:45 – 17:05	**Phagetherapy, Promises and Pitfalls** • **Academic Presenter: Pieter Jan Haas PhD MD**, Medical Microbiologist, *University Medical Center Utrecht*
17:05 – 17:25	**Platform Process for an Autonomous Production of Virus-Like Particles** • **Academic Presenter: Simon Baukmann** , Research Associate, *Institute for Separation and Process Technology, TU Clausthal*
17:25 – 17:55	**Q&A Discussion** • **Regulatory Moderator: Veronika Jekerle PhD**, Head of Pharmaceutical Quality, Human Medicines, *European Medicines Agency* • **Regulatory Panelist: Helerin Eiche PhD**, Quality Assessor of Biological Medicinal Products, *State Agency of Medicines (Estonia)* • **Regulatory Panelist: Daniel Holý Ing**, Quality Assessor of Biological Medicinal Products, *State Institute for Drug Control (Czechia)* • **Academic Panelist: Simon Baukmann** , Research Associate, *Institute for Separation and Process Technology, TU Clausthal* • **Academic Panelist: Pieter Jan Haas PhD MD**, Medical Microbiologist, *University Medical Center Utrecht*
17:55 – 17:55	**End of Conference Day 1 & Networking Event**

Wednesday, 24 September

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08:00 – 16:00	**Registration Hours**
09:00 – 09:05	**Welcome to Day 2**
	Session 4: Digitalization Enhancing Sustainability **Moderator: Michael R. De Felippis PhD**, Senior Vice President - Research Bioproduct Research and Development, *Eli*

Lilly and Company

09:05 – 10:35	09:05 – 09:25	**Accelerating E&L Safety Assessments for SU Technology in Biopharmaceutical Manufacturing Using Software Solutions** • **Presenter: Ina Pahl** , Senior Scientist, *Sartorius Stedim Biotech GmbH*
	09:25 – 09:45	**Data Driven Utilities Consumption Analysis for Cycle Time and Resource Optimization in Biomanufacturing** • **Presenter: Gabriele Vigani** , Global Product Manager, Digital Solutions, *Fedegari Group*
	09:45 – 10:05	**Towards a Digital and Circular Approach to Process Design and Product Distribution** • **Academic Presenter: Maria Papathanasiou PhD**, Associate Professor (UK Senior Lecturer), *Department of Chemical Engineering, Imperial College London*
	10:05 – 10:35	**Q&A Discussion** • **Moderator: Michael R. De Felippis PhD**, Senior Vice President - Research Bioproduct Research and Development, *Eli Lilly and Company* • **Panelist: Gabriele Vigani** , Global Product Manager, Digital Solutions, *Fedegari Group* • **Academic Panelist: Maria Papathanasiou PhD**, Associate Professor (UK Senior Lecturer), *Department of Chemical Engineering, Imperial College London* • **Panelist: Ina Pahl** , Senior Scientist, *Sartorius Stedim Biotech GmbH*
10:35 – 11:05		**Networking Coffee Break, Poster Session & Exhibition**
11:05 – 12:35		**Session 5: Accelerating Patient Access - Development and Regulatory Approaches** **Moderator: Cristiana Campa PhD**, External CMC Intelligence Lead, *GSK*
	11:05 – 11:25	**CEPI's Regulatory Preparedness Framework for Public Health Emergencies: first pilot with Accumulus for regulatory review of the CMC Platform Best Practices** • **Presenter: Olga Rovira MSc**, Regulatory Affairs Senior Consultant, *CEPI*
	11:25 – 11:45	**Accelerating Vaccine Development: Synergizing Bench Experiments with Computational Innovations** • **Presenter: Daniela Stranges PhD**, Director, *GlaxoSmithKlein (GSK)*
	11:45 – 12:05	**Leveraging Collaborative Assessment to Accelerate Approval and Patient Access: Case Studies From Pre-Approval and Post-Approval** • **Presenter: Divya Jain** , Senior CMC Scientist, *Merck Sharp and Dhome*
	12:05 – 12:35	**Q&A Discussion** • **Moderator: Cristiana Campa PhD**, External CMC Intelligence Lead, *GSK* • **Panelist: Daniela Stranges PhD**, Director, *GlaxoSmithKlein (GSK)* • **Panelist: Olga Rovira MSc**, Regulatory Affairs Senior Consultant, *CEPI* • **Panelist: Divya Jain** , Senior CMC Scientist, *Merck Sharp and Dhome*
12:35 – 13:35		**Networking Lunch Break, Poster Session & Exhibition**
		Closing Plenary: Innovation, Digitalization and the Regulatory Roadmap of the Future

13:35 – 14:50	**Moderator: Sabine Hauck Dr**, Consultant, . 13:35 – 13:50: **Development and Deployment of an End-to-End Digital Twin for Biopharmaceutical Manufacturing** • **Presenter: Loric Petruzzi PhD**, CMC Consultant, *Körber Pharma Software* 13:50 – 14:10: **Catalysing Progress: How EMA Supports Innovation in Pharmaceutical Development and Manufacturing** • **Regulatory Presenter: Veronika Jekerle PhD**, Head of Pharmaceutical Quality, Human Medicines, *European Medicines Agency* 14:10 – 14:50: **Plenary Discussion** • **Moderator: Sabine Hauck Dr**, Consultant, . • **Moderator: Maria Papathanasiou PhD**, Associate Professor (UK Senior Lecturer), *Department of Chemical Engineering, Imperial College London* • **Regulatory Panelist: Veronika Jekerle PhD**, Head of Pharmaceutical Quality, Human Medicines, *European Medicines Agency* • **Panelist: Anna Czwarno Ms.Eng.**, Regulatory, Manufacturing & Supply Director, Vaccines Europe, *Vaccines Europe* • **Panelist: Loric Petruzzi PhD**, CMC Consultant, *Körber Pharma Software*
14:50 – 15:20	**Networking Coffee Break, Poster Session & Exhibition**
15:20 – 15:25	**Passport Raffle**
15:25 – 15:30	**Best Poster Presentation**
15:30 – 16:25	**Interactive Round Table Session** **Moderator: Sabine Hauck Dr**, Consultant, .
16:25 – 16:35	**Co-Chairs Conference Summary**
16:35 – 16:40	**Closing Remarks & Farewell**
16:40 – 16:40	**End of Conference**