PDA BioManufacturing Conference 2025

Agenda

Tuesday, 23 September

CEST Daylight Time (UTC +2:00)

08:00 – 17:30	**Registration Hours** Mainport
09:00 – 09:10	**Welcome and Introduction** Panorama 5-9 **Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*
09:10 – 09:20	**Welcome from the Co-Chairs** Panorama 5-9 **Co-Chair: Sabine Hauck Dr**, Consultant, . **Co-Chair: Maria Papathanasiou PhD** Associate Professor in Process Systems Engineering *Department of Chemical Engineering, Imperial College London*
09:20 – 11:30	**Opening Plenary: Shaping Regulations for the Future** Panorama 5-9 **Moderator: Maria Papathanasiou PhD**, Associate Professor in Process Systems Engineering, *Department of Chemical Engineering, Imperial College London* **Moderator: Sabine Hauck Dr** Consultant .

09:20 – 09:45	**Regulatory Update from EMA** Panorama 5-9 • **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** Panorama 5-9 • **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** Panorama 5-9 • **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** Panorama 5-9 • **Presenter: Josh Eaton MS**, Senior Director, Scientific and Regulatory Affairs, *PDA*

	10:45 – 11:30	**Plenary Discussion** Panorama 5-9 • **Moderator: Maria Papathanasiou PhD**, Associate Professor in Process Systems Engineering, *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** Mainport
12:00 – 13:15		**Session 1: Tackling Manufacturing Challenges** Panorama 5-9 Modern biomanufacturing faces increasing pressure to meet regulatory expectations while staying agile and efficient. This session highlights how innovation in packaging, equipment, and process technologies is driving compliance and efficiency in modern biomanufacturing. A new framework for applying functional equivalence in equipment and materials will be discussed, enabling streamlined lifecycle management and reduced regulatory burden. Presenters will show how Ready-to-Use/Ready-to-Fill components and supplier-driven particle control support Annex 1 implementation and improved contamination control. The session also introduces an advancement in continuous freeze-drying, offering faster cycles, lower energy use, and seamless scale-up. Case studies will illustrate practical implementation and regulatory alignment. Attendees will gain insights into how suppliers and manufacturers can collaborate to modernize bioprocesses and strengthen supply reliability. Join this session to gain actionable insights into how modern solutions can strengthen quality, accelerate innovation, and reduce risk in biomanufacturing. **Moderator: Sebastian Groel PhD**, Manager Formulation Technology, *Daiichi Sankyo Europe*
	12:00 – 12:15	**Leveraging Functional Equivalence of Process Manufacturing Equipment and Materials to Streamline Lifecycle Management of Commercial Biologics Processes** Panorama 5-9 • **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** Panorama 5-9 • **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** Panorama 5-9 • **Academic Presenter: Thomas De Beer PhD**, Professor, *Ghent University*
	12:45 – 13:15	**Q&A Discussion** Panorama 5-9 • **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

Mainport

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

13:15 – 13:45

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** Mainport • **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** Mainport • **Poster Presenter: Nicola Powell** , Phorum Director, *BioPhorum*
13:15 – 13:45	**Advanced Solutions for Aseptic Material Transfer** Mainport • **Poster Presenter: Valentina Ratti MSc enginnering**, Strategic Marketing Manager, *FEDEGARI*
13:15 – 13:45	**In-Line UV Spectrometry Monitoring in Cleaning Validation** Mainport • **Poster Presenter: Brian Bosso** , Technical Service Manager, *STERIS*
13:15 – 13:45	**Strategic Changes to a Legacy Cleaning Approach Result a in More Sustainable Process** Mainport • **Poster Presenter: Dijana Hadziselimovic** , ,
13:15 – 13:45	**Impact of Poloxamer 188 Crystallization on Viral Stability in Lyophilized Formulations** Mainport • **Poster Presenter: Angela Valentic** , Process Expert, *Boehringer Ingelheim*
13:15 – 13:45	**Application of Single-Use Systems in Biomanufacturing: Contamination Control Strategies For Particulate Matter** Mainport • **Poster Presenter: Klaus R. Wormuth PhD**, Principal Scientist, *Sartorius*
13:15 – 13:45	**PUPSIT Simulation During Process-Specific Bacterial Retention Testing (PUPSIT-BCT)** Mainport • **Poster Presenter: Yvonne Groß Dipl.-Ing (FH)**, Senior Scientist, *Sartorius Stedim Biotech*
	Improving VHP Distribution for Decontamination using Magnetically Levitated Fans

	13:15 – 13:45	Mainport • **Poster Presenter: Ivana Festera PhD**, Scientific Advisor, *Levitronix GmbH*
	13:15 – 13:45	**Trending and Pattern Recognition for Annex 1** Mainport • **Poster Presenter: Susan B. Cleary EMBA**, Director Product Development, *Novatek*
	13:15 – 13:45	**Refolution´s Sustainable Freezing Systems** Mainport • **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** Mainport • **Poster Presenter: Ivo Buzzi** , ,
	13:15 – 13:45	**Sartopore® Evo — Embracing A PFAS Free Future in Bio-Pharmaceutical Fill & Finish Operations** Mainport • **Poster Presenter: Holger Bromm** , Principal Expert Filtration, *Sartorius Stedim Biotech GmbH*
13:15 – 14:30	**Networking Lunch Break, Poster Session & Exhibition** Mainport	
14:30 – 15:55	**Session 2: Novel Analytical Approaches to Elucidate Various Product Attributes** Panorama 5-9 In this session, we will discuss various analytical approaches at gaining further insights of critical quality attributes. As many products are becoming more and more complex it takes even more innovative ways to carefully comprehend where issues may stem from. Here, we show that this can be tackled via subvisible particle analytical tools combined with AI, well-orchestrated DoE studies to study stability attributes, and non-intrusive analytical methods to confirm product profile. **Moderator: Pepijn Burgers PhD**, Scientific Director Biologics AD , *JnJ Innovative Medicine*	
	14:30 – 14:40	**Interactive Questionnaire Session** Panorama 5-9 • **Moderator: Pepijn Burgers PhD**, Scientific Director Biologics AD , *JnJ Innovative Medicine*
	14:40 – 14:55	**Characterizing Biologics Using wNMR** Panorama 5-9 • **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** Panorama 5-9 • **Presenter: Olga Labovitiadi PhD**, Scientific Associate Director , *JnJ Innovative Medicines Drug product Development and Delivery*
		Innovative Tools to Support Particle Identification and Characterization in (Bio)Pharmaceuticals

	15:10 – 15:25	Panorama 5-9 • **Presenter: Daniel Demminger Dr**, Senior Scientist, *Coriolis Pharma Research GmbH*
	15:25 – 15:55	**Q&A Discussion** Panorama 5-9 • **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** Mainport	
16:25 – 17:55	**Session 3: New Treatment Modalities: Bacteriophages and Virus-Like Particles** Panorama 5-9 The session will cover specialised product modalities such as bacteriophage therapy and virus-like particles used as a carrier for vaccination and general treatments against many pathogens. Four speakers with diverse backgrounds covering regulatory, clinical and academic manufacturing backgrounds will share their insights into development, manufacture and clinically use of such modalities and discuss how challenges including selection of targeted bacteriophage cocktails, characterisation and genetic stability as well as digital twins (DTs) applications for Quality-by-Design Processes and the introduction of PAT systems can be overcome. The session also discusses how regulators are supporting specialised treatment modalities including an introduction to EMA's draft guidance for bacteriophage therapies and explore how the EU legal framework could evolve to better cater for such innovative products in the future. **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** Panorama 5-9 • **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** Panorama 5-9 • **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** Panorama 5-9 • **Academic Presenter: Simon Baukmann** , Research Associate, *Institute for Separation and Process Technology, TU Clausthal*
		Q&A Discussion Panorama 5-9 • **Regulatory Moderator: Veronika Jekerle PhD**, Head of Pharmaceutical Quality, Human Medicines, *European Medicines Agency*

	17:25 – 17:55	• **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

CEST Daylight Time (UTC +2:00)

08:00 – 16:00	**Registration Hours** Mainport	
09:00 – 09:05	**Welcome to Day 2** Panorama 5-9	
09:05 – 10:35	**Session 4: Digitalization Enhancing Sustainability** Panorama 5-9 Digital transformation is revolutionizing biopharmaceutical manufacturing driving smarter, more efficient, and environmentally sustainable operations across the entire value chain. Join this session to explore how digital tools can accelerate your organization's sustainability goals. Discover a software solution that minimizes solvent usage in extractables and leachables assessments. Learn how a digital system for utility analytics can optimize processes resulting in shorter cycle times, lower costs, and a reduced environmental footprint. Gain valuable insights into a digital framework that supports sustainable process design and product distribution. **Moderator: Michael R. De Felippis PhD**, Senior Vice President - Research Bioproduct Research and Development, *Eli Lilly and Company*	
	09:05 – 09:25	**Accelerating E&L Safety Assessments for SU Technology in Biopharmaceutical Manufacturing Using Software Solutions** Panorama 5-9 • **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** Panorama 5-9 • **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** Panorama 5-9 • **Academic Presenter: Maria Papathanasiou PhD**, Associate Professor in Process Systems Engineering, *Department of Chemical Engineering, Imperial College London*
		Q&A Discussion Panorama 5-9 • **Moderator: Michael R. De Felippis PhD**, Senior Vice President - Research Bioproduct Research and Development, *Eli Lilly and Company*

	10:05 – 10:35	• **Panelist: Gabriele Vigani** , Global Product Manager, Digital Solutions, *Fedegari Group* • **Academic Panelist: Maria Papathanasiou PhD**, Associate Professor in Process Systems Engineering, *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** Mainport	
11:05 – 12:35	**Session 5: Accelerating Patient Access - Development and Regulatory Approaches** Panorama 5-9 This session will offer visibility on some key enablers of Global Accelerated Access of vaccines and therapeutics, with perspectives from key experts from Industry and the Coalition of Pandemic Preparedness Innovations (CEPI). The opening talk will cover insightful learnings from CEPI's first pilot with Accumulus for regulatory review of the CEPI Best Practices on Comparability and Process Validation; reflection will be shared on how this approach could be instrumental to support acceleration and harmonization of regulatory agencies' assessment especially in case of health emergencies. The subsequent talk, from GSK, will illustrate how accelerated development can be enabled also by advanced CMC strategies and innovation, and the final presentation, from MSD, will share examples of collaborative assessments to accelerate regulatory approval of vaccines for infectious disease and therapeutic products. The panel discussion will be a key opportunity to further expand understanding of key challenges and opportunities associated with accelerating patient access. **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** Panorama 5-9 • **Presenter: Olga Rovira MSc**, Regulatory Affairs Senior Consultant, *CEPI*
	11:25 – 11:45	**Accelerating Vaccine Development: Synergizing Bench Experiments with Computational Innovations** Panorama 5-9 • **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** Panorama 5-9 • **Presenter: Divya Jain** , Senior CMC Scientist, *Merck Sharp and Dhome*
	12:05 – 12:35	**Q&A Discussion** Panorama 5-9 • **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** Mainport	
	Closing Plenary: Innovation, Digitalization and the Regulatory Roadmap of the Future Panorama 5-9	

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** Panorama 5-9 • **Presenter: Loric Petruzzi PhD**, CMC Consultant, *Körber Pharma Software* 13:50 – 14:10: **Catalysing Progress: How EMA Supports Innovation in Pharmaceutical Development and Manufacturing** Panorama 5-9 • **Regulatory Presenter: Veronika Jekerle PhD**, Head of Pharmaceutical Quality, Human Medicines, *European Medicines Agency* 14:10 – 14:50: **Plenary Discussion** Panorama 5-9 • **Moderator: Sabine Hauck Dr**, Consultant, . • **Moderator: Maria Papathanasiou PhD**, Associate Professor in Process Systems Engineering, *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** Mainport
15:20 – 15:25	**Passport Raffle** Panorama 5-9
15:25 – 15:30	**Best Poster Presentation** Panorama 5-9
15:30 – 16:25	**Interactive Round Table Session** Panorama 5-9 Join our open discussion round to engage with all stakeholders. We selected a wide range of topics to meet your interest, ranging from AI through patient centric specifications and stability modelling to overcoming shortages. Feel free to bring your questions and hear the opinion of the BioManufatcuring community **Moderator: Sabine Hauck Dr**, Consultant, .
16:25 – 16:35	**Co-Chairs Conference Summary** Panorama 5-9
16:35 – 16:40	**Closing Remarks & Farewell** Panorama 5-9
16:40 – 16:40	**End of Conference** Panorama 5-9