Agenda

PDA BioManufacturing Conference 2025

Tuesday, 23 September

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, **PhD**, Consultant, *Consultant*

Co-Chair: Maria Papathanasiou, **PhD**, Associate Professor (UK Senior Lecturer), *Department of Chemical Engineering, Imperial College London*

09:20 – 11:30

Opening Plenary

Moderator: Maria Papathanasiou, **PhD**, Associate Professor (UK Senior Lecturer), *Department of Chemical Engineering, Imperial College London*

Moderator: Sabine Hauck, **PhD**, Consultant, *Consultant*

09:20 – 09:45

Titel to be announced

Regulatory Presenter: Brian Dooley

09:45 – 09:55

Title to be announced

09:55 – 10:20

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*

10:20 – 10:45

Europe at the Cutting Edge of Manufacturing Innovation and Competitiveness

Presenter: Mónica Perea-Vélez, **MSc, PhD**, CMC Advocacy and Policy Director, *GSK*

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, **PhD**, Consultant, *Consultant*

Regulatory Panelist: Steffen Gross, **PhD**, Head Section Qualtiy and Non-clinical Evaluation of Antibody Therapeutics, *Paul-Ehrlich-Institute*

Regulatory Panelist: Brian Dooley

11:30 – 12:00

Networking Coffee Break, Poster Session & Exhibition

12:00 – 13:15

Session 1: Tackling Manufacturing Challenges

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

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*

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13:15 – 14:30

Networking Lunch Break, Poster Session & Exhibition

13:45 – 14:30

Guided Poster Walk

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

14:30 – 15:55

Session 2: Analytics

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 , *Drug product Development and Delivery Johnson & Johnson Innovative Medicines*

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*

15:25 – 15:55

Q&A Discussion

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 , *Drug product Development and Delivery Johnson & Johnson Innovative Medicines*

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: Phages – New Promising Treatment Modality

Regulatory Moderator: Veronika Jekerle, **PhD**, Head of Pharmaceutical Quality, Human Medicines, *European Medicines Agency*

16:25 – 16:45

Personalized Bacteriophage Therapy

Academic Presenter: Pieter-Jan Haas

16:45 – 17:05

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)*

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

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17:55 – 17:55

End of Conference Day 1 & Networking Event

Wednesday, 24 September

09:00 – 09:05

Welcome to Day 2

09:05 – 10:35

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 – 09:25

Data Driven Utilities Consumption Analysis for Cycle Time and Resource Optimization in Biomanufacturing

Presenter: Gabriele Vigani, Global Product Manager, Digital Solutions, *Fedegari Group*

09:25 – 09:45

Towards a Digital and Circular Approach to Process Design and Product Distribution

Co-Chair: Maria Papathanasiou, **PhD**, Associate Professor (UK Senior Lecturer), *Department of Chemical Engineering, Imperial College London*

09:45 – 10:05

Accelerating E&L Safety Assessments for SU Technology in Biopharmaceutical Manufacturing Using Software Solutions

Presenter: Ina Pahl, Senior Scientist, *Sartorius Stedim Biotech GmbH*

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

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Networking Coffee Break, Poster Session & Exhibition

11:05 – 12:35

Session 5: Accelerating Patient Access - Development and Regulatory Approaches

Moderator: Cristiana Campa, **PhD**, Technical R&D Advisor, *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, 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: Derradji Boumrah, **PhD**, Assoc Principal Scientist, Regulatory Affairs, *Merck Sharp & Dohme (UK) Limited*

12:05 – 12:35

Q&A Discussion

Moderator: Cristiana Campa, **PhD**, Technical R&D Advisor, *GSK*

Panelist: Daniela Stranges, **PhD**, Director, *GlaxoSmithKlein (GSK)*

Panelist: Derradji Boumrah, **PhD**, Assoc Principal Scientist, Regulatory Affairs, *Merck Sharp & Dohme (UK) Limited*

Panelist: Olga Rovira, Regulatory Affairs Senior Consultant, *CEPI*

12:35 – 13:35

Networking Lunch Break, Poster Session & Exhibition

13:35 – 14:50

Closing Plenary

Moderator: Sabine Hauck, **PhD**, Consultant, *Consultant*

13:35 – 13:50

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PDA BioManufacturing Conference 2025

Title to be announced

13:50 – 14:10

Title to be announced

Regulatory Presenter: Veronika Jekerle, **PhD**, Head of Pharmaceutical Quality, Human Medicines, *European Medicines Agency*

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, **PhD**, Consultant, *Consultant*

16:25 – 16:35

Co-Chairs Conference Summary

16:35 – 16:40

Closing Remarks & Farewell

16:40 – 16:40

End of Conference