Agenda

PDA BioManufacturing Conference 2024

Tuesday, 24 September

08:00 – 18:00

Registration Open

09:00 – 09:10

Welcoming

Committee Member: Falk Klar, **PhD**, *Parenteral Drug Association*

09:10 – 09:20

Welcome from the Co-Chairs

Co-Chair: Sabine Hauck, **Dr**, EVP Corporate Development & QM, *Leukocare AG*

Co-Chair: Sabine Hauck, **Dr**, EVP Corporate Development & QM, *Leukocare AG*

09:20 – 10:50

Opening Plenary Part I: Addressing Patients Needs

With the theme of this year: Shaping the Future of Biomanufacturing the 6th PDA Biomanufacturing Conference provides you with key trends and latest development in Bioindustry. The first plenary session will focus on our core motivations: serving the patient's needs with an exceptional patient testimony followed by an overview of modern treatment modalities and the current key trends. The regulatory talk will focus then on the update of the ICH Q6.

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

09:20 – 09:50

A Brief Insight Into Life with Multiple Sclerosis

Presenter: Karen Somers

09:50 – 10:20

Development of Antibody Drug Conjugates as Specific and Potent Medicinal Products - A Regulator´s Perspective

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

10:20 – 10:50

ICH Q6 - Quo Vadis

Regulatory Presenter: Mats Welin

10:50 – 11:20

Agenda

PDA BioManufacturing Conference 2024

Networking Coffee Break, Poster Session & Exhibition

11:20 – 12:30

Opening Plenary Part II: Addressing Patients Needs

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Moderator: Elisabeth Vachette, **MA**, BPS Sustainability Business Partner, *Sartorius Stedim FMT SAS*

11:20 – 11:45

Developing Patient Centric Specification for Commercial Biologics: Real World Case Studies

Presenter: Jason Warfel

11:45 – 12:30

Plenary Discussion

Moderator: Elisabeth Vachette, **MA**, BPS Sustainability Business Partner, *Sartorius Stedim FMT SAS*

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

Regulatory Panelist: Mats Welin

Panelist: Jason Warfel

Panelist: Karen Somers

12:30 – 13:45

Networking Lunch Break & Exhibition

13:15 – 13:45

Guided Poster Walk

Moderator: Bianca Bohrer, **Dipl Ing**, Managing Director, *PSM GmbH*

13:45 – 15:30

Session 1 Track A: Processes for New Entities in Freeze-Drying

Unlock the future of biomanufacturing with our session on freeze-drying processes, featuring experts unveiling the latest advancements and technologies. Discover how cutting-edge technologies like vial impedance spectroscopy and Hydrogen Deuterium Mass Spectrometry can revolutionize the stability of biologics, offering you the keys to mastering protein stabilization. Dive into a state-of-the-art lyophilization model that seamlessly integrates thermodynamic principles with heat and mass transfer equations, empowering you to optimize process parameters and ensure unparalleled product quality through predictive modeling and robustness analysis. Uncover innovative solutions to the logistical challenges of oncolytic viruses, including a pioneering formulation that stabilizes these entities for easy

distribution and storage at 2-8 °C, potentially transforming clinical applications and slashing costs. This session is designed to not only inform but also ignite your creativity, driving the next wave of innovation in biopharmaceutical manufacturing. Stay ahead of the curve and elevate your expertise in freeze-drying technology.

Moderator: Julian H. Lenger, **PhD**, Head of Laboratory Parenteral Drug Development, *Bayer AG*

13:45 – 02:10

Developments in In-Line and Off-Line Analytics Applied to Freeze Drying of Biologicals

Presenter: Paul Matejtschuk, **PhD FRSC CChem** , Section Head Formulation Science , *MHRA*

14:10 – 14:35

Building Robustness into the Primary Drying Phase of Lyophilization: A Modelling Framework and Use Cases for Biopharmaceuticals

Presenter: Andrea Arsiccio, **PhD**, Senior Scientist, *Coriolis Pharma*

14:35 – 15:00

Solving the Deep-Frozen Challenge – Lyophilization of an Oncolytic Virus

Presenter: Thomas Kriehuber

15:00 – 15:30

Q&A

Moderator: Julian H. Lenger, **PhD**, Head of Laboratory Parenteral Drug Development, *Bayer AG*

Panelist: Andrea Arsiccio, **PhD**, Senior Scientist, *Coriolis Pharma*

Panelist: Thomas Kriehuber

Panelist: Paul Matejtschuk, **PhD FRSC CChem** , Section Head Formulation Science , *MHRA*

13:45 – 15:30

Session 1 Track B: CMC Strategies for Vaccines Biomanufacturing

This session will provide some insights into CMC's innovative Strategies for Vaccines Biomanufacturing, covering development and lifecycle considerations. We will start with an overview of PDA Vaccine Interest Group (VIG) activities in this field, reporting recent activities and key topics of interest voted by PDA vaccine experts. Ideas and comments from the audience will be taken into consideration by the PDA VIG and reflected in future VIG tasks as needed. The session will then propose industry examples of "patient-centric" CMC strategies, based on experience from two vaccine manufacturers; reflection on product (formulation) development and specifications setting will be offered, illustrating challenges and opportunities associated with different vaccine types.

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

13:45 – 14:10

Vaccines Interest Group Session - Our 2024 journey!

Presenter: Sabrina Restrepo, **PhD**, Director, Vaccines - Technical Product Leadership, *Merck & Co., Inc.*

14:10 – 14:35

Patient-Centric Development for Vaccines

Presenter: Frédéric Mathot, **PhD**, Associate Director, Scientific Leader, *GSK*

14:35 – 15:00

Applying Prior Knowledge and Patient Centric Based Considerations to Specification Setting

Presenter: Pepijn Burgers

15:00 – 15:30

Q&A

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

Panelist: Sabrina Restrepo, **PhD**, Director, Vaccines - Technical Product Leadership, *Merck & Co., Inc.*

Panelist: Frédéric Mathot, **PhD**, Associate Director, Scientific Leader, *GSK*

Panelist: Pepijn Burgers

15:30 – 16:00

Networking Coffee Break, Poster Session & Exhibition

16:00 – 17:45

Session 2 Track A: Opportunities for Vaccine Access

This session will explore opportunities for increased access to vaccines globally. As important as vaccines are to health throughout the world, there have been barriers to access. We will explore the use of different technologies to increase the speed of development and approval. We will also look at the regulatory side impacting access. As markets and supply become more global, there is a need to have regulatory processes that approach new technologies and routine work in a more harmonized manner and to expand the use of reliance.

Moderator: Mic McGoldrick, Technical Advocacy and Policy - CMC, *Merck Sharp & Dohme Corp. LLC*

16:00 – 16:25

Fast Evolving Vaccine Innovation Landscape

Presenter: Anna Czwarno, **Ms.Eng.**, Regulatory, Manufacturing & Supply Director, Vaccines Europe, *Vaccines Europe*

16:25 – 16:50

Building Health Emergency Preparedness by Harnessing the Potential of Vaccine Platforms

Presenter: Ramin Sabet-Azad, **PhD**, CMC Lead, *The Coalition for Epidemic Preparedness Innovations (CEPI)*

16:50 – 17:15

Regulatory Global Convergence, Harmonization, and Reliance

Presenter: Navdip Ghai, Director - Regulatory Affairs CMC, *Merck Sharpe & Dohme*

17:15 – 17:45

Q&A

Moderator: Mic McGoldrick, Technical Advocacy and Policy - CMC, *Merck Sharp & Dohme Corp. LLC*

Panelist: Anna Czwarno, **Ms.Eng.**, Regulatory, Manufacturing & Supply Director, Vaccines Europe, *Vaccines Europe*

Panelist: Ramin Sabet-Azad, **PhD**, CMC Lead, *The Coalition for Epidemic Preparedness Innovations (CEPI)*

Panelist: Navdip Ghai, Director - Regulatory Affairs CMC, *Merck Sharpe & Dohme*

16:00 – 17:45

Session 2 Track B: Innovation in Biomanufacturing

Grow your knowledge as experts from academia and industry share their innovative approaches to biopharmaceutical manufacturing. Beginning with upstream process operations, learn how a novel cell-free protein system can enable the production of therapeutic proteins without relying on cell culture and utilizing only DNA, buffer components, and the transcription and translation machinery extracted from cells. This synthetic strategy offers faster protein production and greater control relative to conventional cell culture processes. Moving on to the downstream process, discover how high-temperature inactivation can serve as an orthogonal tool to clear heat-susceptible contaminants. Case studies will demonstrate how heat treatment can be applied to inactivate host cell-derived enzymes to ensure product stability and as an alternative for viral inactivation. The survey of biopharmaceutical manufacturing innovation included in this session concludes with a focused discussion on polysorbate degradation. Instability of this widely used excipient in drug product formulations presents a major technical challenge for biopharmaceutical manufacturing and quality control. Recommendations are provided for designing a comprehensive control strategy to minimize risks.

Moderator: Michael R De Felippis, **PhD**, Senior Vice President - Research Bioproduct Research and Development, *Eli Lilly and Company*

16:00 – 16:25

Cell-Free Manufacturing of Proteins

Presenter: Matthias Steiger

16:25 – 16:50

Application and Utilization of Heat Inactivation as a Downstream Purification Tool in Biomanufacturing Processes

Presenter: Colette Carmody Culhane, **MSc.**, Senior Advisor, Manufacturing Science and Technology, *Eli Lilly & Company*

16:50 – 17:15

Polysorbate Control Strategies in Biopharmaceuticals

Co-Presenter: Roman Mathaes, **PhD**, CEO, *Clear Solutions Laboratories*

Co-Presenter: Atanas Koulov, **PhD**, Chief Scientific Officer, *Clear Solutions Laboratories AG*

17:15 – 17:45

Q&A

Moderator: Michael R De Felippis, **PhD**, Senior Vice President - Research Bioproduct Research and Development, *Eli Lilly and Company*

Panelist: Matthias Steiger

Panelist: Colette Carmody Culhane, **MSc.**, Senior Advisor, Manufacturing Science and Technology, *Eli Lilly & Company*

Panelist: Roman Mathaes, **PhD**, CEO, *Clear Solutions Laboratories*

Panelist: Atanas Koulov, **PhD**, Chief Scientific Officer, *Clear Solutions Laboratories AG*

18:30 – 22:00

Networking Event

Wednesday, 25 September

08:00 – 08:45

Track A: Interest Group Session: Advanced Manufacturing and Applied Process Digitalization (former Biomanufacturing IG)

The Advanced Manufacturing and Applied Process Digitalization IG will be providing an update on two active Task Force Initiatives underway within the PDA. The Mobile Manufacturing Task Forces currently working on a Points to Consider Paper, which is planned to be issued this year and will provide an update on the key points/questions it will address. The AI Task Force will provide an update on the roadmap it created, a summary of the gap assessment, digitalization implementation survey results, AI Glossary, and future activities. The updates will be followed by an open discussion with the IG members on current hot topics.

Moderator: Toni Manzano, Co-Founder and CSO of Aizon, and Team Leader, AI in Operations (AIO), *Aizon and United Nations, professor at the URV*

Moderator: Peter J. Makowenskyj, **MEng**, Director of Design Consulting, *G-CON*

08:00 – 08:45

Track B: Interest Group Session: Lyophilization

Moderator: Anthony Cannon

08:00 – 16:00

Registration Open

09:00 – 10:45

Session 3 Track A: Digital Tools Shaping Future Biomanufacturing

This session explores how digital tools are transforming the biomanufacturing industry by enhancing efficiency, precision, and innovation. We will delve into key topics such as the integration of AI and machine learning for predictive analytics and process optimization, the influence of regulatory agencies on industry digitization, and the acceleration of manufacturing processes through digitalization. Participants will gain insights from industry experts, discover the latest digital innovations, and learn how these tools can foster scalability, flexibility, and sustainability in biomanufacturing operations.

Moderator: Adithya Balasubramanian, Director, *ten23 health AG*

09:00 – 09:25

The Key Role of AI in Biomanufacturing and Good Practices to Implement it

Presenter: Toni Manzano, Co-Founder and CSO of Aizon, and Team Leader, AI in Operations (AIO), *Aizon and United Nations, professor at the URV*

09:25 – 09:50

A Regulatory Framework Enabling Digital Innovation in Manufacturing

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

09:50 – 10:15

Accelerated Process Development using End-to-End Digital Twins

Presenter: Thomas Zahel, **PhD**, Head of Innovation, *Körber Pharma*

10:15 – 10:45

Q&A

Moderator: Adithya Balasubramanian, Director, *ten23 health AG*

Panelist: Toni Manzano, Co-Founder and CSO of Aizon, and Team Leader, AI in Operations (AIO), *Aizon and United Nations, professor at the URV*

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

Panelist: Thomas Zahel, **PhD**, Head of Innovation, *Körber Pharma*

09:00 – 10:45

Session 3 Track B: Future Techniques in Freeze-Drying

Step into the future of biomanufacturing with our second session on freeze-drying and lyophilization processes, highlighting the future techniques and technological breakthroughs in the machinery as well as process design. Discover how an innovative air-cooling technology offers a reduced global warming potential and ensures high production reliability. Explore a pioneering continuous lyophilization technique for mRNA-lipid nanoparticles that enhances long-term stability and maintains product integrity even after extended storage at room temperature. Gain valuable insights into the thermal interactions during biopharmaceutical freezing, focusing on how vial arrangement impacts nucleation temperature distribution and overall product quality. Remain at the recent technology of industry developments and deepen your expertise in freeze-drying technology.

Moderator: Sebastian Groel

09:00 – 09:25

Sustainable Refrigeration Technologies: Overview and Implementation of Innovative Air-Cooling Technology for Freeze-Drying Processes

Co-Presenter: Fabian Plaum, **M.Eng.**, Sales Management, *HOF Sonderanlagenbau GmbH*

Co-Presenter: Christian Sonntag, **MS**, Senior Project Manager, *Roche Diagnostics GmbH*

09:25 – 09:50

Continuous and Controlled Lyophilization of mRNA-LNPs Based Formulations

Academic Presenter: Thomas De Beer, **PhD**, Professor, *Ghent University*

09:50 – 10:15

Understanding Thermal Interactions in Biopharmaceutical Freezing: Implications for Nucleation Temperature Distribution

Academic Presenter: Roberto Pisano

10:15 – 10:45

Q&A

Moderator: Sebastian Groel

Panelist: Fabian Plaum, **M.Eng.**, Sales Management, *HOF Sonderanlagenbau GmbH*

Panelist: Christian Sonntag, **MS**, Senior Project Manager, *Roche Diagnostics GmbH*

Academic Panelist: Thomas De Beer, **PhD**, Professor, *Ghent University*

Academic Panelist: Roberto Pisano

10:45 – 11:15

Networking Coffee Break, Poster Session & Exhibition

11:15 – 12:45

Session 4 Track A: Fill & Finish Processing

Extractible and leachable studies can represent an important budget over the year and as soon there's a change the process should be revalidated. With the help of a mathematical model, there's now a way to predict the outcome without testing for some change. The tubing can equally have an uptake of VHP leading to oxidation of the active pharmaceutical ingredient, the second presentation goes through a deep analysis of this phenomenon. The last subject will deal with process modeling and how to create consistent computer-generated documentation for fill finish.

Moderator: Yves Mayeresse, Director, *GSK*

11:15 – 11:35

Discovering Equivalence in Extractables & Leachables Assessments of Single-Use Systems: An Advanced Mathematical Methodology

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

11:35 – 11:55

VHP Uptake of Manufacturing Tubing Used for Aseptic Fill-Finish Processes of Biopharmaceutical Drug Products

Presenter: Dilara Ali, **MSc**, PhD Student , *ten23 health*

11:55 – 12:15

Frame-by-Frame - End-to-End: How Advanced Risk Profiling Accelerated the Development of a Robust Manufacturing Setup for a Brand New Kindeva Fill-Finish Site

Co-Presenter: Sebastian Scheler, **Mr.**, Managing Director, *Innerspace GmbH*

Co-Presenter: Jeff Gensler

12:15 – 12:45

Q&A

Moderator: Yves Mayeresse, Director, *GSK*

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

Panelist: Dilara Ali, **MSc**, PhD Student , *ten23 health*

Panelist: Sebastian Scheler, **Mr.**, Managing Director, *Innerspace GmbH*

Panelist: Jeff Gensler

11:15 – 12:45

Session 4 Track B: Sustainability

Enhancing sustainability is an increasingly central concern in the biomanufacturing sector. In this session, experts from industry and EDQM will discuss sustainability initiatives to shape the future of biomanufacturing. We will hear the regulatory perspective on the integration of the 3Rs principles of Replacement, Reduction, and Refinement of animal testing in European Pharmacopoeia texts to promote and protect human and animal health. Through real-life examples, we will illustrate how companies have successfully improved their ESG (Environmental, social, and governance) scores and what benefits they can bring. Finally, consideration and implementation of sustainable water management plans to Recycle, Reuse, Reduce, and Re-purpose water in biomanufacturing will be explored as well as the need for greater collaboration between all stakeholders.

Moderator: Virginie Le Coent

11:15 – 11:35

Sustainability at the EDQM: A Focus on the Ph. Eur. and the 3Rs

Regulatory Presenter: Emmanuelle F Charton, Head of Division B, European Pharmacopoeia Department, *EDQM*

11:35 – 11:55

Enhancing Sustainability ESG Scores in BioManufacturing

Presenter: Philippe Gadal

11:55 – 12:15

Using Sustainable Taxonomy: Recycle, Reuse, Reduce & Re-purpose Water for pharmaceutical Use

Presenter: Durga Prasad Madhavapeddi

12:15 – 12:45

Q&A

Moderator: Virginie Le Coent

Regulatory Panelist: Emmanuelle F Charton, Head of Division B, European Pharmacopoeia Department, *EDQM*

Panelist: Philippe Gadal

Panelist: Durga Prasad Madhavapeddi

12:45 – 13:45

Networking Lunch Break, Poster Session & Exhibition

13:45 – 13:55

Interactive Questionnaire

Moderator: Sabine Hauck, **Dr**, EVP Corporate Development & QM, *Leukocare AG*

13:55 – 14:45

Closing Plenary Part I: Innovative Regulatory Strategies for a Globalized World

Moderator: Sabine Hauck, **Dr**, EVP Corporate Development & QM, *Leukocare AG*

13:55 – 14:20

Title to be Announced

Regulatory Presenter: Robin Levis, CBER, *U.S. FDA*

14:20 – 14:45

Efficiency in Pharmaceutical Life-Cycle Management: Implementing ICH Q12 and Established Conditions

Presenter: Thomas Stangler

14:20 – 14:45

Simultaneous Submission to Multiple Health Authorities Using Accumulus Synergy Platform - Using CMC Platform Best Practices for Comparability Assessments and Manufacturing Process Validation as Pilot

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

Agenda

PDA BioManufacturing Conference 2024

14:45 – 15:15

Networking Coffee Break, Poster Session & Exhibition

15:15 – 15:20

Passport Raffle

15:20 – 16:30

Closing Plenary Part II: Innovative Regulatory Strategies for a Globalized World

Moderator: Sabine Hauck, **Dr**, EVP Corporate Development & QM, *Leukocare AG*

15:20 – 15:45

Simultaneous Submission to Multiple Health Authorities Using Accumulus Synergy Platform - Using CMC Platform Best Practices for Comparability Assessments and Manufacturing Process Validation as Pilot

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

15:20 – 15:50

Title to be Announced

15:45 – 16:30

Plenary Discussion

Moderator: Sabine Hauck, **Dr**, EVP Corporate Development & QM, *Leukocare AG*

Panelist: Thomas Stangler

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

Panelist: Anna Czwarno, **Ms.Eng.**, Regulatory, Manufacturing & Supply Director, Vaccines Europe, *Vaccines Europe*

Regulatory Panelist: Mats Welin

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

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

Regulatory Panelist: Paul Matejtschuk, **PhD FRSC CChem** , Section Head Formulation Science , *MHRA*

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

Regulatory Panelist: Robin Levis, CBER, *U.S. FDA*

16:30 – 16:40

Co-Chair Conference Summary

Co-Chair: Sabine Hauck, **Dr**, EVP Corporate Development & QM, *Leukocare AG*

Co-Chair: Sabine Hauck, **Dr**, EVP Corporate Development & QM, *Leukocare AG*

16:40 – 16:45

Closing Remarks & Farewell

Committee Member: Falk Klar, **PhD**, *Parenteral Drug Association*