2023 PDA BioManufacturing Conference  
Agility and Biomanufacturing Excellence to Meet Patients’ Needs  
12 – 13 September 2023  
Seville, Spain

<table>
<thead>
<tr>
<th>Tuesday, 12 September 2023</th>
<th>09:00 – 17:50</th>
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| 9:00 | Welcome and Introduction | Falk Klar,  
PDA Europe |
| 9:05 | Welcome from the Co - Chairs | Cristiana Campa, GSK  
Elisabeth Vachette, Sartorius |

**Opening Session: Agility and Biomanufacturing Excellence to Meet Patients’ Needs**

Moderators:  
Cristiana Campa, GSK  
Elisabeth Vachette, Sartorius

With the theme of this year: Agility and Biomanufacturing Excellence to meet Patient’s Needs the 5th PDA Biomanufacturing Conference provides key trends and latest development in Bioindustry. The first plenary session will provide extensive reflection on regulatory framework for innovations in Chemistry, Manufacturing and Controls (CMC) for biotherapeutics and vaccines, showcasing opportunities and examples of collaboration between Industry and Regulatory Agencies to drive implementation of new technologies and digital strategies in the biopharmaceutical area. Furthermore, perspectives on accelerated CMC development roadmaps will be provided by CEPI, also reflecting on the interdependency between innovation and rapid access to patients.

| 09:15 | Regulatory Framework for Biomanufacturing Innovations | Mats Welin,  
Medical Products Agency  
Sweden |
| 09:45 | Artificial Intelligence and Digital Twins in Biopharma Manufacturing | Toni Manzano,  
Aizon |
| 10:15 | Quality Innovation Group: Regulatory Support for Innovative Manufacturing and Quality Control Approaches | Marcos Timón,  
Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) |

**10:45 Coffee Break, Poster Session & Exhibition**

| 11:15 | The IMI Inno4Vac Project: A Public-Private Partnership Focussing on Innovations to Accelerate Vaccine Development and Manufacture | Wim Van Molle,  
Sciensano Belgium |
| 11:45 | Phase Appropriate CMC Deliverables for Vaccine Development | Anna Särnefält,  
CEPI |
| 12:10 | Q&A, Panel Discussion |
### Session 1

**Track A**

**Application of AI and ML for Biopharmaceutical Development and Manufacturing**

*Moderator:* Michael De Felippis, Eli Lilly

Artificial Intelligence (AI) and Machine Learning (ML) tools are increasingly being deployed across multiple industries to unlock new value and gain efficiency. The biopharmaceutical industry is recognizing the important role AI/ML can play in improving processes for development and commercialization and accelerating innovative medicines to patients. This session includes three applications of AI/ML including repurposing AI technology implemented at an unrelated industry for a biopharmaceutical manufacturing process, using ML modeling to increase efficiency and probability of technical success for drug candidates in early-phase development, and creating an ML algorithm to optimize excipient selection for biopharmaceutical formulations.

**Track B**

**The Power of Modelling and Microwaves in Lyophilization**

*Moderator:* Julian Lenger, Bayer

Explore the scientific advancements in lyophilization through the application of modeling techniques and the utilization of microwaves. Gain insights into how modeling enhances the optimization of lyophilization cycles by guiding the selection of process parameters for desired product attributes. Discover the impact of the freezing step on drying efficiency and product quality and learn about the influence of controlled nucleation on primary drying simulation accuracy. Dive into the scientific principles of microwave-assisted freeze-drying (MFD), uncovering its potential to significantly reduce drying times while maintaining product integrity. Join us to delve into the scientific aspects of lyophilization optimization and the utilization of innovative technologies.

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<th>Moderator(s)</th>
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<tbody>
<tr>
<td>13:00</td>
<td>Lunch Break, Poster Session &amp; Exhibition</td>
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<tr>
<td>13:45</td>
<td><strong>LIVE Guided Poster Walk</strong> Engage with our Poster Presenters in our Exhibition Hall</td>
<td>Thomas Beutler, GEA Lyophil</td>
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<tr>
<td>14:00</td>
<td>Session 1</td>
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<tr>
<td>14:15</td>
<td>Model-Driven AI in Operations Management: From Space Exploration to Real World Bio-Manufacturing</td>
<td>Jonas Gibaszek, Rombio</td>
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<tr>
<td>14:40</td>
<td>Predicting Holistic Developability Scores for Protein Scaffolds Using Machine Learning</td>
<td>Daniel Pais, Valogenesis Karin Felderer, Pieris</td>
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| 15:05 | Pharmaceuticals | Machine-Learning Acceleration of Biopharmaceutical Formulation Development Using Excipient Prediction Software (ExPreSo) | Estefania Vidal-Henriquez, *Leukocare*  
A Novel Way of Freeze-Drying: Drastic Drying Time Reduction Using Microwave Radiation  
Benjamin Ledermann, *GEA Lyophil* |
| 15:30 |          | Q&A, Discussion                                                               | Q&A, Discussion |
| 16:00 |          | **Coffee Break, Poster Session & Exhibition**                               |                                                                  |
|       | Session 2 | **Track A**  
Advanced Modeling Strategies for Product and Process Understanding | **Moderator:** Sabine Hauck, *Leukocare*  
**Track B**  
Formulation / Fill and Finish | **Moderator:** Yves Mayeresse, *GSK* |

**Modelling of processes bears the two-fold advantage of deeper process understanding and gaining speed. Kinetic modelling is a powerful tool to predict process outcome based on real data and process understanding. The speakers in this session will present the success stories of kinetic modelling for manufacturing process on one side, and stability prediction on the other side.**

The requirements for drug products evolved over the years to obtain better quality. This evolution can come from new rules or from innovation. The first presentation will discuss how important requirements of the European GMP Annex 1:2022 have changed the qualification of cleanrooms.

Continuous environmental monitoring represents one of the most relevant and effective tools to assess in real time the potential risk of contamination in critical environments. With a second presentation we will learn how to design a more resilient vial to physical insults thus minimizing breakage and having better machining capability when compared to existing borosilicate vial. The challenge of implementing these vials and the need to revise USP/EP to broaden the definition of Type I pharmaceutical glass and gaining the approval by US FDA will be explained.
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16:30  Quantifying the Catabolism of CHO Cells to Build Industrially Relevant Kinetic Models  Sergio Rossell, GSK  Environmental and Process Monitoring (Viable and Total Particle) According to the EU GMP Annex 1:2022 - New Requirements and Next Challenges  Diego Bompadre, Rigel Life Sciences

16:55  A Universal Tool for Stability Predictions of Biotherapeutics, Vaccines and In Vitro Diagnostic Products  Didier Clénet & Warren Roche, Sanofi  Regulatory Journey to Approval of a Novel Final Product Container  Navdip Ghai, Merck Sharp & Dohme

17:20  Q&A, Discussion

17:50  End of Conference Day 1 & Networking Event

Wednesday, 13 September 2023  09:00 – 16:45

Session 3  Track A  Track B  Moderator: Michael De Felippis, Eli Lilly  Moderator: Elisabeth Vachette, Sartorius

Track A  Sustainability

Track B  Enhancements in Supply Capacity

While the pharmaceutical industry is recognized for its unique position on creating value to patients and society based on innovations, expectations have raised in recent years to put focus on sustainability. To achieve the goal of climate neutral operations and supply chain within pharmaceutical industry, it is of crucial importance to implement sustainability targets already from the beginning into the design of pharmaceutical products. In the first presentation industrial case studies are presented on how to meet sustainability targets in context of the existing regulatory frameworks, following the second presentation on how strategies can support sustainability, considering both process design and optimization (mAb example) and techno-economic assessment and modeling (viral vector example) by

Drug availability is one of the key drivers of our industry and serving patients means that drug manufacturing processes must be flexible and resilient enough to cope with numerous constraints including current demand variability. This session will focus on 2 aspects having demonstrated their ability to better serve patients, namely by developing novel processes and increasing flexibility and speed to market via process intensification implementation and via rapid process and regulatory scalability for biologics enabling mass production.
## Session 4

### Track A Vaccines

**Moderator:** Yves Mayeresse, GSK

The first presentation will provide general principles on specification setting for different vaccine types, as well as some illustrative examples, showing how to overcome some challenges and providing reflections on future directions as there is no predefined and single set of specifications’ quality attributes for vaccines against a given pathogen, since multiple vaccine platforms can be used for the same target. The next presentation will focus on the PDA technical report 89: Strategies for vaccine development and life cycle management.

### Track B Advances in Biotherapeutics Developments and Life Cycle

**Moderator:** Sabine Hauck, Leukocare

Developments in biotherapeutic manufacturing will be illustrated for antibodies and cell-based therapies. A case study of a commercial platform mAb process and its global post-approval changes will provide lessons learned with respect to ensuring streamlined lifecycle management. The second talk will discuss allogeneic cell therapies and their potential as “off-the-shelf” products.
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Lifestyle Management of a Commercial Platform  
Monoclonal Antibody Process: The Promise of ICH Q12 | Cillian McCabe, *Eli Lilly* |
| 11:15 | Specifications for Vaccines                                                  | Julia O’Neill, *Direxa Consulting*  
What the cell? Next Generation Allogeneic Cell Therapies and Impact on Facility Design | Emily Heffernan, *Arcadis DPS Group* |
| 11:40 | Q&A, Discussion                                                              | Q&A, Discussion                                                             |
| 12:10 | Lunch Break, Poster Session & Exhibition                                     |                                                                            |
| 13:10 | Interactive Questionnaire                                                    |                                                                            |
| 13:20 | Accelerating Access to Vaccines – Next Steps Beyond the Pandemic             | Mic McGoldrick, *Merck Sharp & Dohme*                                       |
| 14:15 | Coffee Break, Poster Session & Exhibition                                    |                                                                            |
| 14:45 | Passport Raffle                                                             |                                                                            |

**Closing Session: Health Emergencies Preparedness for the Future**

*Moderators: Cristiana Campa, GSK  
Elisabeth Vachette, Sartorius*

The closing plenary session will explore progress of implementation of pandemic-related learnings from Industry and Regulators, including concrete initiatives from vaccines developers and new guidance tools from Health Authorities, especially in case of epidemic or pandemic scenarios. We will benefit from key experts and take the opportunity to network and exchange with EMA and FDA, as well as from Global Health-driven organizations like CEPI to accelerate development and supply of biopharmaceuticals and provide innovative tools for comparability assessment and process validation. Our common goal is to meet patient’s needs through agility and biomanufacturing excellence.
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<td>Expedited Product Development – Learning from Pandemics</td>
<td>Anissa Cheung, <em>US FDA</em></td>
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<tr>
<td>15:20</td>
<td>EMA CMC Toolbox: Facilitating Early Access of Biopharmaceuticals in the EU</td>
<td>Elisa Pedone, <em>EMA</em></td>
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<tr>
<td>16:30</td>
<td><strong>Co-Chairs Conference Summary</strong></td>
<td>Cristiana Campa, <em>GSK</em> Elisa Vachette, <em>Sartorius</em></td>
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<tr>
<td>16:40</td>
<td><strong>Closing Remarks &amp; Farewell</strong></td>
<td>Falk Klar, <em>PDA Europe</em></td>
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<tr>
<td>16:45</td>
<td><strong>End of Conference</strong></td>
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*The agenda is subject to change without notice!*