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: Elisabeth Vachette, MA, BPS Sustainability Business Partner, Sartorius Stedim FMT SAS
Co-Chair: Sabine Hauck, Dr, EVP Corporate Development & QM, Leukocare AG

09:20 – 10:50
Opening Plenary Part I: Addressing Patients Needs
Moderator: Elisabeth Vachette, MA, BPS Sustainability Business Partner, Sartorius Stedim FMT SAS

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<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>09:20</td>
<td>A Brief Insight Into Life with Multiple Sclerosis</td>
<td>Karen Somers</td>
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<td>09:50</td>
<td>Development of Antibody Drug Conjugates as Specific and Potent Medicinal Products - A Regulator’s Perspective</td>
<td>Steffen Gross</td>
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<td>10:20</td>
<td>ICH Q6 - Quo Vadis</td>
<td>Mats Welin</td>
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10:50 – 11:20
Networking Coffee Break, Poster Session & Exhibition
11:20 – 12:30

Opening Plenary Part II: Addressing Patients Needs

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

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<td>11:20 – 11:45</td>
<td>Developing Patient Centric Specification for Commercial Biologics: Real World Case Studies</td>
<td><strong>Presenter:</strong> Jason Warfel</td>
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| 11:45 – 12:30 | Plenary Discussion                                                            | **Moderator:** Elisabeth Vachette, MA, BPS Sustainability Business Partner, *Sartorius Stedim FMT SAS*  
**Regulatory Panelist:** Steffen Gross  
**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

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

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<td>13:45 – 02:10</td>
<td>Developments in in Line and Offline Process Testing for Biologicals</td>
<td><strong>Regulatory Presenter:</strong> Paul Matejschuk</td>
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<td>14:10 – 14:35</td>
<td>Building Robustness into the Primary Drying Phase of Lyophilization: A Modelling Framework and Use Cases for</td>
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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*

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

**Panelist**: Thomas Kriehuber

**Regulatory Panelist**: Paul Matejtschuk

13:45 – 15:30

Session 1 Track B: CMC Strategies for Vaccines Biomanufacturing

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

15:30 – 16:00

Networking Coffee Break, Poster Session & Exhibition

16:00 – 17:45

Session 2 Track A: Opportunities for Vaccine Access

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

16:00 – 17:45

Session 2 Track B: Innovation in Biomanufacturing

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

18:30 – 22:00

Networking Event
Wednesday, 25 September

08:00 – 08:45
Interest Group Session: Advanced Manufacturing and Applied Process Digitalization (former Biomanufacturing IG)

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
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

Moderator: Adithya Balasubramanian, Director, ten23 health AG

09:00 – 10:45
Session 3 Track B: Future Techniques in Freeze-Drying

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

   Moderator: Yves Mayeresse, Director, GSK

11:15 – 12:45

Session 4 Track B: Sustainability

   Moderator: Virginie Le Coent

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

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

16:30 – 16:40

Co-Chair Conference Summary

Co-Chair: Elisabeth Vachette, MA, BPS Sustainability Business Partner, Sartorius Stedim FMT SAS

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