Wednesday, 15 May

08:00 – 17:30
Registration Open

09:00 – 09:05
Welcome and Introduction
Committee: Falk Klar PhD PDA Europe

09:05 – 09:15
Welcome from the Co-Chairs
Co-Chair: Simone Biel PhD Senior Regulatory Consultant Merck
Co-Chair: Darren Beckett Sr. Training and R&D Manager Fedegari Technologies Inc

09:15 – 10:45
Opening Plenary Part I: Advancing Aseptic Manufacturing for Safe Medicines - Lessons Learned and Path Forward
Moderator: Simone Biel PhD Senior Regulatory Consultant Merck

  09:15 – 09:45
  Presenter: Hussain Jafri PhD Executive Director World Patients Alliance

  09:45 – 10:15
  Implementation of EU GMP Annex 1 – Inspection Experiences and Expectations
  Regulatory Presenter: Christina Meissner AGES - Austrian Agency for Health and Food Safety

  10:15 – 10:45
  Fit for Future: Sterile Manufacture? A Personal View on Revised EU GMP Annex 1
  Regulatory Presenter: Daniel Mueller PhD Head of GMDP-Inspectorate Regierungspraesidium Tuebingen, Germany

10:45 – 11:15
Networking Coffee Break, Poster Session & Exhibition
11:15 – 12:45

Opening Plenary Part II: Advancing Aseptic Manufacturing for Safe Medicines - Lessons Learned and Path Forward

**Moderator: Simone Biel PhD** Senior Regulatory Consultant *Merck*

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:15 – 11:35</td>
<td>Legacy Cleanrooms and what to do about them</td>
</tr>
<tr>
<td></td>
<td><strong>Presenter:</strong> Tracy Moore <em>Director TM Pharma Group Ltd</em></td>
</tr>
<tr>
<td>11:35 – 11:55</td>
<td>Annex 1 Implementation: A Case Study of the Sterile Production at F. Hoffmann-La Roche Ltd.</td>
</tr>
<tr>
<td></td>
<td><strong>Presenter:</strong> Tarik Cheema</td>
</tr>
<tr>
<td>11:55 – 12:00</td>
<td>Interactive Questionnaire Session</td>
</tr>
<tr>
<td>12:00 – 12:45</td>
<td>Q&amp;A, Panel Discussion</td>
</tr>
<tr>
<td></td>
<td><strong>Moderator:</strong> Simone Biel PhD Senior Regulatory Consultant <em>Merck</em></td>
</tr>
<tr>
<td></td>
<td><strong>Moderator:</strong> Darren Beckett Sr. Training and R&amp;D Manager <em>Fedegari Technologies Inc</em></td>
</tr>
<tr>
<td></td>
<td><strong>Panelist:</strong> Hussain Jafri PhD Executive Director <em>World Patients Alliance</em></td>
</tr>
<tr>
<td></td>
<td><strong>Panelist:</strong> Tarik Cheema</td>
</tr>
<tr>
<td></td>
<td><strong>Panelist:</strong> Tracy Moore <em>Director TM Pharma Group Ltd</em></td>
</tr>
</tbody>
</table>

12:40 – 14:00

Networking Lunch Break & Exhibition

13:30 – 14:00

Guided Poster Walk

14:00 – 15:20

Session 1, Track A: Impact of EU GMP Annex 1 on Lyophilization

**Moderator: Andrea Salmaso PharmD** Corporate Regulatory and Scientific Affairs Manager *Stevanato Group*
14:00 – 14:25

Requirements for Lyophilization in the New Annex 1

**Regulatory Presenter:** Marisa Delbo PharmD Consultant NA

14:25 – 14:50

A Better Approach to APS for Lyophilized Products - APS Approach for Freeze-Drying Process Considering Annex 1 Requirements

**Presenter:** Christian Scarpato Process Engineering Manager Merck

14:50 – 15:20

Q&A, Discussion

**Moderator:** Andrea Salmaso PharmD Corporate Regulatory and Scientific Affairs Manager Stevanato Group

**Panelist:** Marisa Delbo PharmD Consultant NA

**Panelist:** Christian Scarpato Process Engineering Manager Merck

---

14:00 – 15:20

Session 1, Track B: Sustainability in Aseptic Manufacturing

**Moderator:** Paul Devuyst Master Bioengineer Senior Manager Aseptic Technologies GSK

14:00 – 14:25

From Sustainability Ambitions into Action: What About Aseptic Manufacturing?

**Presenter:** Michael Hell PhD Head of Environment / Sustainability Healthcare Operations Merck Healthcare KGaA

14:25 – 14:50

Can We Have Reliable and Fast Sustainability Impact Assessments? Merging Technology, Innovation, and Sustainability

**Presenter:** Alissa Monk Sustainability Lead ten23 health

14:50 – 15:20

Q&A, Discussion

**Moderator:** Paul Devuyst Master Bioengineer Senior Manager Aseptic Technologies GSK

**Panelist:** Michael Hell PhD Head of Environment / Sustainability Healthcare Operations Merck Healthcare KGaA

**Panelist:** Alissa Monk Sustainability Lead ten23 health
15:20 – 15:50
Networking Coffee Break, Poster Session & Exhibition

15:50 – 17:10
Session 2, Track A: Filtration and Closed Systems

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

15:50 – 16:15
PUPSIT in the Revised Annex I – Friend or Foe of the Pharmaceutical Entrepreneur?
Presenter: Manuel Grund Process Engineer Roche Pharmaceuticals

16:15 – 16:40
Contamination Control Strategies in Processing of Frozen Sterile Bulk Drug Product in Single-use Bag Assembly
Presenter: Yuan-An Liu

16:40 – 17:10
Q&A, Discussion
Moderator: Peter J. Makowenskyj MEng Director of Design Consulting G-CON
Panelist: Manuel Grund Process Engineer Roche Pharmaceuticals
Panelist: Yuan-An Liu

15:50 – 17:10
Session 2, Track B: Aseptic Set-Up of Filling Machines

Moderator: Klaus Ullherr Senior Product Manager Syntegon Technology GmbH

15:50 – 16:15
Implementing Annex 1 Guidelines: A Comprehensive Approach to Sterility Assurance for Indirect Product Contact Parts
Presenter: Christian Rust B.S. Chemical and Biomolecular Engineering Technical Operations MSD

16:15 – 16:40
Compliance with New Annex 1 on a Fill/Finish Machine: A Glance into the Future
Presenter: Helen Sauter Dr Director Quality Assurance Vetter Pharma Fertigung GmbH & Co. KG
16:40 – 17:10

Q&A, Discussion

**Moderator:** Klaus Ullherr Senior Product Manager Syntegon Technology GmbH
**Panelist:** Christian Rust B.S. Chemical and Biomolecular Engineering Technical Operations MSD
**Panelist:** Helen Sauter Dr Director Quality Assurance Vetter Pharma Fertigung GmbH & Co. KG

17:10 – 22:00

End of Conference Day 1 & Networking Event

Thursday, 16 May

08:00 – 17:45

Registration Open

09:00 – 10:30

Session 3, Track A: Environmental Monitoring

**Moderator:** Hue Kwon PhD Global Head of Quality Samsung Bioepis

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenters</th>
</tr>
</thead>
</table>
| 09:00  | Total Particle Count – Tubing Qualification at GSK: Lessons Learned           | **Co-Presenter:** Paul Devuyst Master Bioengineer Senior Manager Aseptic Technologies GSK  
**Co-Presenter:** Kurt Jaeques MA Global Aseptic Technologies Lead Monitoring & Control GSK |
| 09:20  | Facility Monitoring in the Daily Practice of a CMO - Annex 1 Fulfillment Without Relying on Settle Plates | **Co-Presenter:** Thomas Müller  
**Co-Presenter:** Marc M. Machauer OEM Coordinator Particle Measuring Systems |
| 09:40  | Automated Reading of Agar Plates Using AI and Machine Learning                | **Presenter:** Andrew Gravett IRCA certified Lead auditor Pharmaceutical QMS Principal Scientist Microbiology AstraZeneca |
| 10:00  |                                                                                | Q&A, Discussion                                                                                |
**Moderator:** Hue Kwon PhD Global Head of Quality *Samsung Bioepis*

**Panelist:** Paul Devuyst Master Bioengineer Senior Manager Aseptic Technologies *GSK*

**Panelist:** Thomas Müller

**Panelist:** Marc M. Machauer OEM Coordinator *Particle Measuring Systems*

**Panelist:** Andrew Gravett IRCA certified Lead auditor Pharmaceutical QMS Principal Scientist Microbiology *AstraZeneca*

09:00 – 10:30

Session 3, Track B: Equipment for Aseptic Processes

**Moderator:** David Keen MRSB CBiol Director Pharmaceutical Microbiology & Consulting *Ecolab Life Sciences*

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00 – 09:20</td>
<td>Annex 1 and 'Good Technology Practice' - Interpretation and Engineering for This Side of Production</td>
<td>Johannes M. Rauschnabel PhD Director Advanced Technology Development and Innovation <em>Syntegon Technology GmbH</em></td>
</tr>
<tr>
<td>09:20 – 09:40</td>
<td>Critical Factors in the Material Transfer Process</td>
<td>Anna Campanella PhD Global Aseptic Processing &amp; Sterility Assurance Lead <em>Takeda Pharmaceuticals International AG</em></td>
</tr>
<tr>
<td>09:40 – 10:00</td>
<td>Title to be announced</td>
<td></td>
</tr>
<tr>
<td>10:00 – 10:30</td>
<td>Q&amp;A, Discussion</td>
<td></td>
</tr>
</tbody>
</table>

**Moderator:** David Keen MRSB CBiol Director Pharmaceutical Microbiology & Consulting *Ecolab Life Sciences*

**Panelist:** Anna Campanella PhD Global Aseptic Processing & Sterility Assurance Lead *Takeda Pharmaceuticals International AG*

**Panelist:** Johannes M. Rauschnabel PhD Director Advanced Technology Development and Innovation *Syntegon Technology GmbH*

10:30 – 11:00

Networking Coffee Break, Poster Session & Exhibition

11:00 – 12:20
### Session 4, Track A: Quality Risk Management

**Moderator:** Richard Denk  
Senior Consulting Aseptic Processing & Containment  
SKAN AG

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:00 – 11:25</td>
<td>A Matter of Uncertainty: Risk Tool Selection With ICH Q9(R1) In Mind</td>
</tr>
</tbody>
</table>
| Presenter    | Amanda McFarland MS  
Senior Consultant  
ValSource, Inc. |
| 11:25 – 11:50 | Using Risk Management to Design Aseptic Process Simulations            |
| Presenter    | Alberto Gonzalez  
Global Sterility Assurance Associate Director  
Takeda         |
| 11:50 – 12:20 | Q&A, Discussion                                                         |
| Moderator    | Richard Denk  
Senior Consulting Aseptic Processing & Containment SKAN AG              |
| Panelist     | Alberto Gonzalez  
Global Sterility Assurance Associate Director  
Takeda         |
| Panelist     | Amanda McFarland MS  
Senior Consultant  
ValSource, Inc. |

11:00 – 12:20

### Session 4, Track B: RABS/Isolator

**Moderator:** Tracy Moore  
Director  
TM Pharma Group Ltd

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:00 – 11:25</td>
<td>APS for Gloveless Isolator Filling Line - Experience and Lessons Learned with the First Installation in Germany</td>
</tr>
</tbody>
</table>
| Presenter    | Thorsten Haefner MBA  
Vice President of Business Development  
PSM GmbH       |
| Presenter    | Martin Novak  
Innovation Manager  
SKAN AG          |
| 11:50 – 12:20 | Q&A, Discussion                                                         |
| Moderator    | Tracy Moore  
Director  
TM Pharma Group Ltd |
| Panelist     | Thorsten Haefner MBA  
Vice President of Business Development  
PSM GmbH       |
Panelist: Martin Novak, Innovation Manager, SKAN AG

12:20 – 13:20
Networking Lunch Break, Poster Session & Exhibition

13:20 – 13:30
Interactive Questionnaire Session

13:30 – 14:15
Closing Plenary Part I
Moderator: Darren Beckett, Sr. Training and R&D Manager, Fedegari Technologies Inc

13:30 – 13:40
Excitement @Syntegon – Insights and Preparation for the Syntegon Factory Tour
Presenter: Klaus Ullherr, Senior Product Manager, Syntegon Technology GmbH

13:40 – 13:55
Introduction of PDA PtC for Sterile Filling
Presenter: Julian Petersen, Head of Business Development, groninger & co. gmbh

13:55 – 14:15
Evolution of GMPs and Why They Are Particularly Important for Sterile Manufacturing
Presenter: Andrew D. Hopkins, Director, Operation Quality QA Audit and Compliance, AbbVie Inc.

14:15 – 14:45
Networking Coffee Break, Poster Session & Exhibition

14:45 – 14:50
Passport Raffle
Moderator: Melanie Decker

14:55 – 16:10
## Closing Plenary Part II

**Moderator:** Darren Beckett Sr. Training and R&D Manager *Fedegari Technologies Inc*

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>14:50</td>
<td>Title to be announced</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Regulatory Presenter:</strong> Brooke K. Higgins MS Branch Chief, OC, CDER <em>U.S. FDA</em></td>
<td></td>
</tr>
<tr>
<td>15:15</td>
<td>Title to be announced</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Regulatory Presenter:</strong> Roberto Conocchia MD GMP Technical Lead <em>European Medicine Agency</em></td>
<td></td>
</tr>
<tr>
<td>15:40</td>
<td>Q&amp;A, Panel Discussion</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Moderator:</strong> Simone Biel PhD Senior Regulatory Consultant <em>Merck</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Moderator:</strong> Darren Beckett Sr. Training and R&amp;D Manager <em>Fedegari Technologies Inc</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Panelist:</strong> Julian Petersen Head of Business Development <em>groninger &amp; co. gmbh</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Panelist:</strong> Andrew D. Hopkins Director, Operation Quality QA Audit and Compliance <em>AbbVie Inc.</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Panelist:</strong> Roberto Conocchia MD GMP Technical Lead <em>European Medicine Agency</em></td>
<td></td>
</tr>
<tr>
<td>16:20</td>
<td>Conference Summary from the Co-Chairs</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Co-Chair:</strong> Simone Biel PhD Senior Regulatory Consultant <em>Merck</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Co-Chair:</strong> Darren Beckett Sr. Training and R&amp;D Manager <em>Fedegari Technologies Inc</em></td>
<td></td>
</tr>
<tr>
<td>16:30</td>
<td>Closing Remarks &amp; Farewell</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Committee:</strong> Falk Klar PhD <em>PDA Europe</em></td>
<td></td>
</tr>
</tbody>
</table>