**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 *Regierungspräsidium Tübingen, Germany*

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

### 2024 PDA Good Aseptic Manufacturing Conference

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
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</table>
| 11:15 | **Opening Plenary Part II: Advancing Aseptic Manufacturing for Safe Medicines - Lessons Learned and Path Forward**  
Moderator: Simone Biel PhD Senior Regulatory Consultant Merck |                              |
| 11:15 | Legacy Cleanrooms and what to do about them                                                   
**Presenter:** Tracy Moore Director **TM Pharma Group Ltd** |                              |
| 11:35 | Annex 1 Implementation: A Case Study of the Sterile Production at F. Hoffmann-La Roche Ltd.   
**Presenter:** Tarik Cheema |                              |
| 11:55 | Interactive Questionnaire Session                                                            |                              |
| 12:00 | Q&A, Panel Discussion                                                                       |                              |
| 12:40 | Networking Lunch Break & Exhibition                                                          |                              |
| 13:30 | Guided Poster Walk                                                                         |                              |
| 14:00 | 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

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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
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<tr>
<td>15:20 – 15:50</td>
<td>Networking Coffee Break, Poster Session &amp; Exhibition</td>
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<td>15:50 – 17:10</td>
<td>Session 2, Track A: Filtration and Closed Systems</td>
<td><strong>Moderator:</strong> Peter J. Makowenskyj MEng Director of Design Consulting <strong>G-CON</strong></td>
<td><strong>Presenter:</strong> Manuel Grund</td>
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<td>15:50 – 16:15</td>
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<td>PUPSIT in the Revised Annex I – Friend or Foe of the Pharmaceutical Entrepreneur?</td>
<td><strong>Presenter:</strong> Manuel Grund</td>
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<td>16:15 – 16:40</td>
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<td>Contamination Control Strategies in Processing of Frozen Sterile Bulk Drug Product in Single-use Bag Assembly</td>
<td><strong>Presenter:</strong> Yuan-An Liu</td>
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<td>16:40 – 17:10</td>
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<td>Q&amp;A, Discussion</td>
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<td>15:50 – 17:10</td>
<td>Session 2, Track B: Aseptic Set-Up of Filling Machines</td>
<td><strong>Moderator:</strong> Klaus Ullherr Senior Product Manager <strong>Syntegon Technology GmbH</strong></td>
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<td>15:50 – 16:15</td>
<td></td>
<td>Implementing Annex 1 Guidelines: A Comprehensive Approach to Sterility Assurance for Indirect Product Contact Parts</td>
<td><strong>Presenter:</strong> Christian Rust B.S. Chemical and Biomolecular Engineering Technical Operations <strong>MSD</strong></td>
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<td>16:15 – 16:40</td>
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<td>Compliance with New Annex 1 on a Fill/Finish Machine: A Glance into the Future</td>
<td><strong>Presenter:</strong> Helen Sauter Dr Director Quality Assurance <strong>Vetter Pharma Fertigung GmbH &amp; Co. KG</strong></td>
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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>
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<th>Time</th>
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<th>Co-Presenters</th>
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<tr>
<td>09:00</td>
<td>Total Particle Count – Tubing Qualification at GSK: Lessons Learned</td>
<td><strong>Co-Presenter:</strong> Paul Devuyst Master Bioengineer Senior Manager Aseptic Technologies GSK&lt;br&gt;<strong>Co-Presenter:</strong> Kurt Jaecques MA Global Aseptic Technologies Lead Monitoring &amp; Control GSK</td>
</tr>
<tr>
<td>09:20</td>
<td>Facility Monitoring in the Daily Practice of a CMO - Annex 1 Fulfillment Without Relying on Settle Plates</td>
<td><strong>Co-Presenter:</strong> Thomas Müller&lt;br&gt;<strong>Co-Presenter:</strong> Marc M. Machauer OEM Coordinator Particle Measuring Systems</td>
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<td>09:40</td>
<td>Automated Reading of Agar Plates Using AI and Machine Learning</td>
<td><strong>Presenter:</strong> Andrew Gravett IRCA certified Lead auditor Pharmaceutical QMS Principal Scientist Microbiology AstraZeneca</td>
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10:00 – 10:30
Q&A, Discussion
Agenda

2024 PDA Good Aseptic Manufacturing Conference

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

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| 09:00 | Annex 1 and 'Good Technology Practice' - Interpretation and Engineering for This Side of Production  
       Presenter: Johannes M. Rauschnabel PhD Director Advanced Technology Development and Innovation Syntegon Technology GmbH |
| 09:20 | Critical Factors in the Material Transfer Process  
       Presenter: Anna Campanella PhD Global Aseptic Processing & Sterility Assurance Lead Takeda Pharmaceuticals International AG |
| 10:00 | Title to be announced |

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

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<tr>
<td>11:00 – 11:25</td>
<td>A Matter of Uncertainty: Risk Tool Selection With ICH Q9(R1) In Mind</td>
<td>Amanda McFarland MS</td>
<td>Senior Consultant</td>
<td>ValSource, Inc.</td>
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<td>11:25 – 11:50</td>
<td>Using Risk Management to Design Aseptic Process Simulations</td>
<td>Alberto Gonzalez</td>
<td>Global Sterility Assurance Associate Director</td>
<td>Takeda</td>
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<td>11:50 – 12:20</td>
<td>Q&amp;A, Discussion</td>
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**Panelists:**
- Alberto Gonzalez  Global Sterility Assurance Associate Director  Takeda
- Amanda McFarland MS  Senior Consultant  ValSource, Inc.

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Session 4, Track B: RABS/Isolator

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

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<td>11:00 – 11:25</td>
<td>APS for Gloveless Isolator Filling Line - Experience and Lessons Learned with the First Installation in Germany</td>
<td>Thorsten Haefner MBA</td>
<td>Vice President of Business Development</td>
<td>PSM GmbH</td>
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<tr>
<td>11:50 – 12:20</td>
<td>Q&amp;A, Discussion</td>
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**Panelists:**
- Thorsten Haefner MBA  Vice President of Business Development  PSM GmbH
- Tracy Moore  Director  TM Pharma Group Ltd
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

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<td>Regulatory Presenter: Brooke K. Higgins MS Branch Chief, OC, CDER U.S. FDA</td>
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<td>15:15</td>
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<td>Regulatory Presenter: Roberto Conocchia MD GMP Technical Lead European Medicine Agency</td>
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<td>16:30</td>
<td>Closing Remarks &amp; Farewell</td>
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<td>Committee: Falk Klar PhD PDA Europe</td>
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