**Agenda**

2024 PDA Good Aseptic Manufacturing Conference

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**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
<table>
<thead>
<tr>
<th>Time</th>
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<tr>
<td>11:15 – 12:45</td>
<td><strong>Opening Plenary Part II: Advancing Aseptic Manufacturing for Safe Medicines - Lessons Learned and Path Forward</strong></td>
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<td><strong>Moderator:</strong> Simone Biel PhD</td>
<td>Senior Regulatory Consultant <em>Merck</em></td>
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<td>11:15 – 11:35</td>
<td>Title to be announced</td>
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<tr>
<td><strong>Presenter:</strong> Tracy Moore</td>
<td>Director <em>TM Pharma Group Ltd</em></td>
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<td>11:35 – 11:55</td>
<td><strong>Annex 1 Implementation: A Case Study of the Sterile Production at F. Hoffmann-La Roche Ltd.</strong></td>
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<td><strong>Presenter:</strong> Tarik Cheema</td>
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<td>11:55 – 12:00</td>
<td><strong>Interactive Questionnaire Session</strong></td>
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<td>12:00 – 12:45</td>
<td><strong>Q&amp;A, Panel Discussion</strong></td>
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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* |
### Session 1, Track B: Sustainability in Aseptic Manufacturing

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

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<td>14:00 – 14:25</td>
<td>From Sustainability Ambitions into Action: What About Aseptic Manufacturing?</td>
<td><strong>Presenter:</strong> Michael Hell PhD Head of Environment / Sustainability Healthcare Operations Merck Healthcare KGaA</td>
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<tr>
<td>14:25 – 14:50</td>
<td>Can We Have Reliable and Fast Sustainability Impact Assessments? Merging Technology, Innovation, and Sustainability</td>
<td><strong>Presenter:</strong> Alissa Monk Sustainability Lead ten23 health</td>
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<tr>
<td>14:50 – 15:20</td>
<td>Q&amp;A, Discussion</td>
<td><strong>Moderator:</strong> Paul Devuyst Master Bioengineer Senior Manager Aseptic Technologies GSK</td>
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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*

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<td>15:50 – 16:15</td>
<td>PUPSIT in the Revised Annex I – Friend or Foe of the Pharmaceutical Entrepreneur?</td>
<td>Manuel Grund</td>
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15:50 – 17:10

Session 2, Track B: Aseptic Set-Up of Filling Machines
**Moderator:** Klaus Ullherr Senior Product Manager *Syntegon Technology GmbH*

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<td>15:50 – 16:15</td>
<td>Implementing Annex 1 Guidelines: A Comprehensive Approach to Sterility Assurance for Indirect Product Contact Parts</td>
<td>Christian Rust B.S. Chemical and Biomolecular Engineering Technical Operations <em>MSD</em></td>
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<td>16:15 – 16:40</td>
<td>Compliance with New Annex 1 on a Fill/Finish Machine: A Glance into the Future</td>
<td>Helen Sauter Dr Director Quality Assurance <em>Vetter Pharma Fertigung GmbH &amp; Co. KG</em></td>
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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

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| 09:00 – 09:20 | Total Particle Count – Tubing Qualification at GSK: Lessons Learned                              | **Co-Presenter:** Paul Devuyyst Master Bioengineer Senior Manager Aseptic Technologies GSK  
**Co-Presenter:** Kurt Jaecques MA Global Aseptic Technologies Lead Monitoring & Control GSK |
| 09:20 – 09:40 | Facility Monitoring in the Daily Practice of a CMO - Annex 1 Fulfillment Without Relying on Settle Plates | **Co-Presenter:** Thomas Müller  
**Co-Presenter:** Marc Machauer |
| 09:40 – 10:00 | 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 – 10:30 | 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 Machauer
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

09:00 – 09:20

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 – 09:40

Critical Factors in the Material Transfer Process

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

09:40 – 10:00

Title to be announced

10:00 – 10:30

Q&A, Discussion

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
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

11:00 – 11:25

A Matter of Uncertainty: Risk Tool Selection With ICH Q9(R1) In Mind

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.

Session 4, Track B: RABS/Isolator

Moderator: Tracy Moore Director TM Pharma Group Ltd

11:00 – 11:25

APS for Gloveless Isolator Filling Line - Experience and Lessons Learned with the First Installation in Germany

Presenter: Thorsten Haefner MBA Vice President of Business Development PSM GmbH

11:25 – 11:50


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*

14:50 – 15:15

Title to be announced

**Regulatory Presenter:** Brooke K. Higgins MS  Branch Chief, OC, CDER  *U.S. FDA*

15:15 – 15:40

Title to be announced

**Regulatory Presenter:** Roberto Conocchia MD  GMP Technical Lead  *European Medicine Agency*

15:40 – 16:20

Q&A, Panel Discussion

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

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

**Panelist:** Julian Petersen  Head of Business Development  *groninger & co. gmbh*

**Panelist:** Andrew D. Hopkins  Director, Operation Quality QA Audit and Compliance  *AbbVie Inc.*

**Panelist:** Roberto Conocchia MD  GMP Technical Lead  *European Medicine Agency*

16:20 – 16:30

Conference Summary 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*

16:30 – 16:35

Closing Remarks & Farewell

**Committee:** Falk Klar PhD  *PDA Europe*