Wednesday, 15 May

09:00 – 09:05

Welcome and Introduction

Presenter: Falk Klar PhD *PDA Europe*

09:05 – 09:15

Welcome from the Co-Chairs

Presenter: Simone Biel PhD Senior Regulatory Consultant *Merck*

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

09:15 – 10:45

Opening Plenary Part I

Moderator: Simone Biel PhD Senior Regulatory Consultant *Merck*

09:15 – 09:45


Presenter: Hussain Jafri

09:45 – 10:15

Title to be announced

10:15 – 10:45

Title to be announced

10:45 – 11:15

Coffee Break, Poster Session & Exhibition

11:15 – 12:40

Opening Plenary Part II

Moderator: Simone Biel PhD Senior Regulatory Consultant *Merck*

11:15 – 11:45

Annex 1 Implementation: A Case Study of the Sterile Production at F. Hoffmann-La Roche Ltd.
**Agenda**

**2024 PDA Good Aseptic Manufacturing Conference**

**Presenter: Tarik Cheema**

11:55 – 12:40

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: Hussain Jafri

Panelist: Tarik Cheema

12:40 – 14:00

Lunch Break, Poster Session & 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 Nuova Ompi Srl

**14:00 – 14:25**

The Interpretation of the New Part on Lyophilizates / Requirements for Lyophilization in the New Annex 1

**Regulatory Presenter: Marisa Delbo**

**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 Nuova Ompi Srl

Panelist: Marisa Delbo

Panelist: Christian Scarpato Process Engineering Manager Merck
### Session 1, Track B: Sustainability in Aseptic Manufacturing

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>14:00 – 14:25</td>
<td>From Sustainability Ambitions into Action: What About Aseptic Manufacturing?</td>
</tr>
<tr>
<td></td>
<td><strong>Presenter:</strong> Michael Hell</td>
</tr>
<tr>
<td>14:25 – 14:50</td>
<td>Can We Have Reliable and Fast Sustainability Impact Assessments? Merging Technology, Innovation, and Sustainability</td>
</tr>
<tr>
<td></td>
<td><strong>Presenter:</strong> Alissa Monk</td>
</tr>
<tr>
<td>14:50 – 15:20</td>
<td>Q&amp;A, Discussion</td>
</tr>
<tr>
<td></td>
<td><strong>Moderator:</strong> Paul Devuyst Master Bioengineer Senior Manager Aseptic Technologies <em>GSK</em></td>
</tr>
<tr>
<td></td>
<td><strong>Panelist:</strong> Michael Hell</td>
</tr>
<tr>
<td></td>
<td><strong>Panelist:</strong> Alissa Monk</td>
</tr>
</tbody>
</table>

### Coffee Break, Poster Session & Exhibition

15:20 – 15:50

### Session 2, Track A: Filtration and Closed Systems

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>15:50 – 16:15</td>
<td>PUPSIT in the Revised Annex 1 – Friend or Foe of the Pharmaceutical Entrepreneur?</td>
</tr>
<tr>
<td></td>
<td><strong>Presenter:</strong> Manuel Grund</td>
</tr>
<tr>
<td>16:15 – 16:40</td>
<td>Contamination Control Strategies in Processing of Frozen Sterile Bulk Drug Product in Single-use Bag Assembly</td>
</tr>
<tr>
<td></td>
<td><strong>Presenter:</strong> Yuan-An Liu</td>
</tr>
</tbody>
</table>
Agenda
2024 PDA Good Aseptic Manufacturing Conference

16:40 – 17:10
Q&A, Discussion

Moderator: Peter J. Makowenskyj MEng Director of Sales Engineering G-CON Manufacturing Inc
Panelist: Manuel Grund
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

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
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

09:00 – 10:30
Session 3, Track A: Environmental Monitoring

Moderator: Hue Kwon PhD Global Head of Quality Samsung Bioepis
09:00 – 09:20

Total Particle Count – Tubing Qualification at GSK: Lessons Learned

Co-Presenter: Paul Devuyst 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 Rauschnabel

09:20 – 09:40

Critical Factors in the Material Transfer Process

Presenter: Anna Campanella
<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:40 – 10:00</td>
<td>Selection of Materials for Autoclave Sterilization Process: 'When Used in Aseptic Processing, the Packaging Should Be of Low Particle Generation' - Annex 1</td>
<td><strong>Presenter:</strong> Sara Iacoponi MD Product Specialist Pharmaclean® AM Instruments</td>
</tr>
</tbody>
</table>
| 10:00 – 10:30| Q&A, Discussion                                                                  | **Moderator:** David Keen MRSB CBiol Director Pharmaceutical Microbiology & Consulting Ecolab Life Sciences  
**Panelist:** Anna Campanella  
**Panelist:** Sara Iacoponi MD Product Specialist Pharmaclean® AM Instruments  
**Panelist:** Johannes Rauschnabel |
| 10:30 – 11:00| 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| Risk Tool Selection With ICH Q9(R1) In Mind                                       | **Presenter:** Amanda McFarland MS Senior Consultant ValSource, Inc.           |
| 11:25 – 11:50| Embracing the Challenge of APS Strategy and Design                               | **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>Topic</th>
<th>Presenter</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>
<td>Thorsten Haefner MBA Vice President of Business Development <em>PSM GmbH</em></td>
</tr>
</tbody>
</table>
| 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

Lunch Break, Poster Session & Exhibition

13:20 – 13:30

Interactive Questionnaire Session

13:30 – 14:20

**Closing Plenary Part I**

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:30 – 13:55</td>
<td>Title to be announced</td>
</tr>
</tbody>
</table>
13:55 – 14:20
Title to be announced

14:20 – 14:50
Coffee Break, Poster Session & Exhibition

14:50 – 14:55
Passport Raffle
Moderator: Sabine Hartmann

14:55 – 16:10
Closing Plenary Part II
Moderator: Darren Beckett Sr. Training and R&D Manager Fedegari Technologies Inc

14:55 – 15:10
Introduction of PDA PtC for Sterile Filling
Presenter: Julian Petersen Head of Business Development groninger & co. gmbh

15:10 – 15:30
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.

15:30 – 16:10
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.

16:10 – 16:20
Conference Summary from the Co-Chairs
Presenter: Simone Biel PhD Senior Regulatory Consultant Merck
Presenter: Darren Beckett Sr. Training and R&D Manager Fedegari Technologies Inc

16:20 – 16:30
Excitement @Syntegon – Insights and Preparation for the Syntegon Factory Tour

Presenter: Klaus Ullherr Senior Product Manager Syntegon Technology GmbH

16:30 – 16:35
Closing Remarks & Farewell

Presenter: Falk Klar PhD PDA Europe