## Agenda

**2024 PDA Good Aseptic Manufacturing Conference**

### Wednesday, 15 May

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter/Details</th>
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<tbody>
<tr>
<td>09:00 – 09:05</td>
<td>Welcome and Introduction</td>
<td>Presenter: Falk Klar PhD, PDA Europe</td>
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<td>09:05 – 09:15</td>
<td>Welcome from the Co-Chairs</td>
<td>Presenter: Simone Biel PhD, Senior Regulatory Consultant, Merck</td>
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<td>Presenter: Darren Beckett, Sr. Training and R&amp;D Manager, Fedegari Technologies Inc</td>
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<tr>
<td>09:15 – 10:45</td>
<td>Opening Plenary Part I</td>
<td>Moderator: Simone Biel PhD, Senior Regulatory Consultant, Merck</td>
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<tr>
<td>09:45 – 10:15</td>
<td>Title to be announced</td>
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<td>10:15 – 10:45</td>
<td>Title to be announced</td>
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<tr>
<td>10:45 – 11:15</td>
<td>Coffee Break, Poster Session &amp; Exhibition</td>
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<tr>
<td>11:15 – 12:40</td>
<td>Opening Plenary Part II</td>
<td>Moderator: Simone Biel PhD, Senior Regulatory Consultant, Merck</td>
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<tr>
<td>11:15 – 11:45</td>
<td>Annex 1 Implementation: A Case Study of the Sterile Production at F. Hoffmann-La Roche Ltd.</td>
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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

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<th>Time</th>
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<tr>
<td>14:00</td>
<td>From Sustainability Ambitions into Action: What About Aseptic Manufacturing?</td>
<td>Michael Hell</td>
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<td>14:25</td>
<td>Can We Have Reliable and Fast Sustainability Impact Assessments? Merging Technology, Innovation, and Sustainability</td>
<td>Alissa Monk</td>
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<td>14:50</td>
<td>Q&amp;A, Discussion</td>
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<td>15:20</td>
<td>Coffee Break, Poster Session &amp; Exhibition</td>
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Session 2, Track A: Filtration and Closed Systems

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

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<tr>
<td>15:50</td>
<td>PUPSIT in the Revised Annex 1 – Friend or Foe of the Pharmaceutical Entrepreneur?</td>
<td>Manuel Grund</td>
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<tr>
<td>16:15</td>
<td>Contamination Control Strategies in Processing of Frozen Sterile Bulk Drug Product in Single-use Bag Assembly</td>
<td>Yuan-An Liu</td>
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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
09:40 – 10:00
Selection of Materials for Autoclave Sterilization Process: 'When Used in Aseptic Processing, the Packaging Should Be of Low Particle Generation' - Annex 1

**Presenter:** Sara Iacoponi MD Product Specialist Pharmaclean® AM Instruments

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 – 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

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

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**

13:30 – 13:55
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<td>Passport Raffle</td>
<td>Moderator: Sabine Hartmann</td>
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<td>Closing Plenary Part II</td>
<td>Moderator: Darren Beckett Sr. Training and R&amp;D Manager Fedegari Technologies Inc</td>
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<td>14:55 – 15:10</td>
<td>Introduction of PDA PtC for Sterile Filling</td>
<td>Presenter: Julian Petersen Head of Business Development groninger &amp; co. gmbh</td>
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<td>15:10 – 15:30</td>
<td>Evolution of GMPs and Why They Are Particularly Important for Sterile Manufacturing</td>
<td>Presenter: Andrew D. Hopkins Director, Operation Quality QA Audit and Compliance AbbVie Inc.</td>
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<td>16:10 – 16:20</td>
<td>Conference Summary from the Co-Chairs</td>
<td>Presenter: Simone Biel PhD Senior Regulatory Consultant Merck</td>
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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