<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter/Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>Welcome and Introduction</td>
<td>Falk Klar PhD PDA Europe</td>
</tr>
<tr>
<td>09:05</td>
<td>Welcome from the Co-Chairs</td>
<td>Simone Biel PhD Senior Regulatory Consultant Merck</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Darren Beckett Sr. Training and R&amp;D Manager Fedegari Technologies Inc.</td>
</tr>
<tr>
<td>09:15</td>
<td>Opening Plenary Part I</td>
<td>Simone Biel PhD Senior Regulatory Consultant Merck</td>
</tr>
<tr>
<td>10:45</td>
<td>Coffee Break, Poster Session &amp; Exhibition</td>
<td></td>
</tr>
<tr>
<td>11:15</td>
<td>Opening Plenary Part II</td>
<td>Simone Biel PhD Senior Regulatory Consultant Merck</td>
</tr>
<tr>
<td></td>
<td>Annex 1 Implementation: A Case Study of the Sterile Production at F. Hoffmann-La Roche Ltd.</td>
<td></td>
</tr>
</tbody>
</table>
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*
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Track B: Sustainability in Aseptic Manufacturing</th>
</tr>
</thead>
<tbody>
<tr>
<td>14:00 – 14:25</td>
<td>From Sustainability Ambitions into Action: What About Aseptic Manufacturing?</td>
<td>Moderator: Paul Devuyst Master Bioengineer Senior Manager Aseptic Technologies GSK Presenter: Michael Hell</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Track A: Filtration and Closed Systems</th>
</tr>
</thead>
</table>
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 Jaeques 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>Event</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>Session Title</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:00</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>

<table>
<thead>
<tr>
<th>Time</th>
<th>11:50 – 12:20 Q&amp;A, Discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Moderator:</strong> Tracy Moore Director <em>TM Pharma Group Ltd</em></td>
</tr>
<tr>
<td></td>
<td><strong>Panelists:</strong> Thorsten Haefner MBA Vice President of Business Development <em>PSM GmbH</em> Martin Novak</td>
</tr>
</tbody>
</table>

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>Session Title</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:30</td>
<td>Title to be announced</td>
<td></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
Agenda
2024 PDA Good Aseptic Manufacturing Conference

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