Wednesday, 15 May

08:00 – 17:30

Registration Open

09:00 – 09:05

Welcome and Introduction
Alte Stuttgarter Reithalle

Committee Member: Falk Klar PhD PDA Europe

09:05 – 09:15

Welcome from the Co-Chairs
Alte Stuttgarter Reithalle

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
Alte Stuttgarter Reithalle

Through insightful keynote presentations, interactive discussions, and case studies, participants will explore the challenges and achievements in Annex 1 implementation. Join us for this thought-provoking session as we collectively reflect on the progress made thus far, identify areas for improvement, and lay the groundwork for a harmonized approach to aseptic manufacturing that ensures the continued delivery of safe medicines to patients worldwide.

Moderator: Simone Biel PhD Senior Regulatory Consultant Merck

09:15 – 09:45

Alte Stuttgarter Reithalle

Presenter: Hussain Jafri PhD Executive Director World Patients Alliance

09:45 – 10:15

Implementation of EU GMP Annex 1 – Inspection Experiences and Expectations
Alte Stuttgarter Reithalle

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
Alte Stuttgarter Reithalle

Regulatory Presenter: Daniel Mueller PhD Head of GMDP-Inspectorate Regierungspraesidium Tuebingen, Germany
10:45 – 11:15

Networking Coffee Break, Poster Session & Exhibition

11:15 – 12:45

Opening Plenary Part II: Advancing Aseptic Manufacturing for Safe Medicines - Lessons Learned and Path Forward

Alte Stuttgarter Reithalle

Through insightful keynote presentations, interactive discussions, and case studies, participants will explore the challenges and achievements in Annex 1 implementation. Join us for this thought-provoking session as we collectively reflect on the progress made thus far, identify areas for improvement, and lay the groundwork for a harmonized approach to aseptic manufacturing that ensures the continued delivery of safe medicines to patients worldwide.

Moderator: Simone Biel PhD Senior Regulatory Consultant Merck

11:15 – 11:35

Title to be announced

Alte Stuttgarter Reithalle

Presenter: Tracy Moore Director TM Pharma Group Ltd

11:35 – 11:55

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

Alte Stuttgarter Reithalle

Presenter: Tarik Cheema PhD End to End Contamination Control Manager F. Hoffmann-La Roche AG

11:55 – 12:00

Interactive Questionnaire Session

Alte Stuttgarter Reithalle

12:00 – 12:45

Q&A, Panel Discussion

Alte Stuttgarter Reithalle

Moderator: Simone Biel PhD Senior Regulatory Consultant Merck

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

Panelist: Hussain Jafri PhD Executive Director World Patients Alliance

Panelist: Tarik Cheema PhD End to End Contamination Control Manager F. Hoffmann-La Roche AG

Panelist: Tracy Moore Director TM Pharma Group Ltd

12:40 – 14:00
Networking Lunch Break & Exhibition
Saal MARITIM & Lobby Empore

13:30 – 14:00

Guided Poster Walk
Lobby Empore

14:00 – 15:20

Session 1, Track A: Impact of EU GMP Annex 1 on Lyophilization
Alte Stuttgarter Reithalle

The new Annex 1 of the GMP introduces new requirements relating to the entire freeze-drying process including product transfer. Now you have the opportunity to dive into the main aspects of the new requirements by the analysis of a senior GMP inspector who worked with the Italian Ministry of Health and the Italian Medicines Agency for more than 20 years. You will also be involved in a case study that for the development of an Aseptic Process Simulation for lyophilized products, that mimics as closely as possible the routine aseptic manufacturing process with a deep dive into simulation of lyophilization justified by scientific and risk-based approach.

**Moderator:** Andrea Salmaso PharmD Corporate Regulatory and Scientific Affairs Manager Stevanato Group

14:00 – 14:25

Requirements for Lyophilization in the New Annex 1
Alte Stuttgarter Reithalle

**Regulatory Presenter:** Marisa Delbo PharmD Consultant N/A

14:25 – 14:50

A Better Approach to APS for Lyophilized Products - APS Approach for Freeze-Drying Process Considering Annex 1 Requirements
Alte Stuttgarter Reithalle

**Presenter:** Christian Scarpato Process Engineering Manager Merck

14:50 – 15:20

Q&A, Discussion
Alte Stuttgarter Reithalle

**Moderator:** Andrea Salmaso PharmD Corporate Regulatory and Scientific Affairs Manager Stevanato Group

**Panelist:** Marisa Delbo PharmD Consultant N/A

**Panelist:** Christian Scarpato Process Engineering Manager Merck

14:00 – 15:20

Session 1, Track B: Sustainability in Aseptic Manufacturing

Sustainability is a core value within the whole industry today and the pharmaceutical industry – aseptic process is not an exception. In this session, we will first give an insight into how design, technology, and innovation will participate in setting up sustainable solutions reducing our global impact on the environment by
overviewing big levers e.g. WFI, Steam generation, HVAC, circular economy (Single use and Take-back program). Then focus will be given to Big Data and AI to model material impact assessment. While discussing performance and growth, the success of the industry remains that the only way to continue to supply and deliver sustainably is to deliver safety, and compliance in an efficient way.

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

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<tr>
<th>Time</th>
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<tr>
<td>14:00 – 14:25</td>
<td>From Sustainability Ambitions into Action: What About Aseptic Manufacturing? &lt;br&gt; <strong>Presenter:</strong> Michael Hell PhD Head of Environment / Sustainability Healthcare Operations <em>Merck Healthcare KGaA</em></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 &lt;br&gt; <strong>Presenter:</strong> Alissa Monk Sustainability Lead <em>ten23 health</em></td>
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<tr>
<td>14:50 – 15:20</td>
<td>Q&amp;A, Discussion &lt;br&gt; <strong>Moderator:</strong> Paul Devuyst Master Bioengineer Senior Manager Aseptic Technologies <em>GSK</em> &lt;br&gt; <strong>Panelist:</strong> Michael Hell PhD Head of Environment / Sustainability Healthcare Operations <em>Merck Healthcare KGaA</em> &lt;br&gt; <strong>Panelist:</strong> Alissa Monk Sustainability Lead <em>ten23 health</em></td>
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<td>15:20 – 15:50</td>
<td>Networking Coffee Break, Poster Session &amp; Exhibition &lt;br&gt; Saal MARITIM &amp; Lobby Empore</td>
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<td>15:50 – 17:10</td>
<td>Session 2, Track A: Filtration and Closed Systems &lt;br&gt; <em>Alte Stuttgarter Reithalle</em> &lt;br&gt; At the heart of patient safety, aseptic processing is a critical component of drug product manufacturing and ensuring Integrity of one’s process is paramount. During this session, we will have two subject matter experts on the subject speak about their experiences around filtration and single use assembly integrity. They will assess the impact of regulations and implications on safety as well as extreme process conditions and steps which should be taken to ensure proper compliance. &lt;br&gt; <strong>Moderator:</strong> Peter J. Makowenskyj MEng Director of Design Consulting <em>G-CON</em></td>
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<td>15:50 – 16:15</td>
<td>PUPSIT in the Revised Annex I – Friend or Foe of the Pharmaceutical Entrepreneur? &lt;br&gt; <em>Alte Stuttgarter Reithalle</em> &lt;br&gt; <strong>Presenter:</strong> Manuel Grund Process Engineer <em>Roche Pharmaceuticals</em></td>
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<td>16:15 – 16:40</td>
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Session 2, Track B: Aseptic Set-Up of Filling Machines

With the requirements of the new Annex 1, the aseptic set-up of a filling machine gets really challenging. In former times you could use the VHP cycle as the final sterilization step. This is not possible anymore. Indirect product contact parts have to be (ideally steam-) sterilized and installed after the VHP cycle. The track shows two different approaches that are both relevant these days: One with an existing isolator line where you use enhanced “classical” methods to install the steam sterilized parts. And a completely new developed machine with a gloveless isolator. Where you do a steam sterilization for the indirect product contact parts and a fully automatic aseptic transfer and installation by using RTP-ports and a robot. For the filling path both solutions are using pre-sterilized single use filling systems.

Moderator: Klaus Ullherr Senior Product Manager Syntegon Technology GmbH
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

This session will cover the latest developments in environmental monitoring (EM). The presenters will discuss how the data is utilized to adapt the new and updated approach for a better EM including the improvements enhanced to be compliant with Annex 1. The session will address new innovative ways to evaluate real time continuous air monitoring. Two case studies will be presented, lesson learned from implementing total particle count tubing qualification on non-viable particle count systems and Automated Reading of Agar Plates using AI. Attendees will gain insights into the latest techniques in EM, associated challenges and learnings, and how these advancements can be applied to impact our industry.

Moderator: Hue Kwon PhD Advisory consultant GLS Advisors LLC

09:00 – 09:20

Total Particle Count – Tubing Qualification at GSK: Lessons Learned
Alte Stuttgarter Reithalle

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

Title to be announced
Alte Stuttgarter Reithalle

Co-Presenter: Marc M. Machauer OEM Coordinator Particle Measuring Systems

Co-Presenter: Marc M. Machauer OEM Coordinator Particle Measuring Systems

09:40 – 10:00

Automated Reading of Agar Plates Using AI and Machine Learning
Alte Stuttgarter Reithalle

Presenter: Andrew Gravett Principal Scientist Microbiology AstraZeneca

10:00 – 10:30

Q&A, Discussion
Alte Stuttgarter Reithalle

Moderator: Hue Kwon PhD Advisory consultant GLS Advisors LLC

Panelist: Paul Devuyst Master Bioengineer Senior Manager Aseptic Technologies GSK

Panelist: Marc M. Machauer OEM Coordinator Particle Measuring Systems
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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<th>Time</th>
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| 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  
**Presenter:** David Keen MRSB CBiol Director Pharmaceutical Microbiology & Consulting Ecolab Life Sciences |
| 10:00 – 10:30 | Q&A, Discussion  
**Moderator:** Tracy Moore Director TM Pharma Group Ltd  
**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:** David Keen MRSB CBiol Director Pharmaceutical Microbiology & Consulting Ecolab Life Sciences |

10:30 – 11:00

Networking Coffee Break, Poster Session & Exhibition  
Saal MARITIM & Lobby Empore

11:00 – 12:20

Session 4, Track A: Quality Risk Management  
Alte Stuttgarter Reithalle
Concerning the EU GMP Annex 1, QRM Quality Risk Management includes the Contamination Control Strategy CCS with all procedures and processes for the safe production of the sterile pharmaceutical product. An essential component of quality risk management is the ICH Q9 to identify the possible risks in the production of the sterile product and to integrate them into the contamination control strategy. In the Aseptic Process Simulation APS, the entire process is checked by all operators to ensure the sterility of the pharmaceutical drug.

**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 Senior Consultant 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 Global Sterility Assurance Associate Director Takeda</td>
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| 11:50 – 12:20 | Q&A, Discussion | Richard Denk Senior Consulting Aseptic Processing & Containment SKAN AG  
Amanda McFarland MS Senior Consultant ValSource, Inc.  
Alberto Gonzalez Global Sterility Assurance Associate Director Takeda |

**Session 4, Track B: RABS/Isolator**

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

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<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 PSM GmbH</td>
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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 MSc  Technology Lead SKAN AG

12:20 – 13:20

Networking Lunch Break, Poster Session & Exhibition  
Saal MARITIM & Lobby Empore

13:20 – 13:30

Interactive Questionnaire Session  
Alte Stuttgarter Reithalle

13:30 – 14:15

Closing Plenary Part I  
Alte Stuttgarter Reithalle

**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  
Alte Stuttgarter Reithalle

**Presenter:** Klaus Ullherr  Senior Product Manager Syntegon Technology GmbH

13:40 – 13:55

Introduction of PDA PtC for Aseptic 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  
Saal MARITIM & Lobby Empore
14:45 – 14:50

Passport Raffle
Alte Stuttgarter Reithalle

Moderator: Melanie Decker

14:55 – 16:10

Closing Plenary Part II
Alte Stuttgarter Reithalle

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

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<td>14:50</td>
<td>Remote presentation title to be announced</td>
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<td><strong>Regulatory Presenter:</strong> Brooke K. Higgins MS Branch Chief, OC, CDER U.S. FDA</td>
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<td>15:15</td>
<td>Remote presentation to be announced</td>
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<td><strong>Regulatory Presenter:</strong> Roberto Conocchia MD GMP Technical Lead European Medicine Agency</td>
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<td>Q&amp;A, Panel Discussion</td>
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<td><strong>Panelist:</strong> Roberto Conocchia MD GMP Technical Lead European Medicine Agency</td>
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<td>16:20</td>
<td>Conference Summary from the Co-Chairs</td>
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<td>Alte Stuttgarter Reithalle</td>
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16:30 – 16:35
Closing Remarks & Farewell
Alte Stuttgarter Reithalle

Committee Member: Falk Klar PhD PDA Europe