**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
Alte Stuttgarter Reithalle

Committee: 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*

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<tr>
<td>11:15 – 11:35</td>
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<td><em>Alte Stuttgarter Reithalle</em></td>
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<td><strong>Presenter:</strong> Tracy Moore Director <em>TM Pharma Group Ltd</em></td>
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<tr>
<td>11:35 – 11:55</td>
<td>Annex 1 Implementation: A Case Study of the Sterile Production at F. Hoffmann-La Roche Ltd. Kaiseraugst</td>
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# 2024 PDA Good Aseptic Manufacturing Conference

## 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*

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<td>14:00 – 14:25</td>
<td>Requirements for Lyophilization in the New Annex 1</td>
<td>Alte Stuttgarter Reithalle</td>
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<td><strong>Regulatory Presenter:</strong> Marisa Delbo PharmD Consulting <em>NA</em></td>
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## 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

| 14:00 – 14:25 |
| From Sustainability Ambitions into Action: What About Aseptic Manufacturing? |
| **Presenter:** Michael Hell PhD Head of Environment / Sustainability Healthcare Operations Merck Healthcare KGaA |

| 14:25 – 14:50 |
| Can We Have Reliable and Fast Sustainability Impact Assessments? Merging Technology, Innovation, and Sustainability |
| **Presenter:** Alissa Monk Sustainability Lead ten23 health |

| 14:50 – 15:20 |
| Q&A, Discussion |

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

**Panelist:** Michael Hell PhD Head of Environment / Sustainability Healthcare Operations Merck Healthcare KGaA

**Panelist:** Alissa Monk Sustainability Lead ten23 health

| 15:20 – 15:50 |
| Networking Coffee Break, Poster Session & Exhibition |
| Saal MARITIM & Lobby Empore |

| 15:50 – 17:10 |
| Session 2, Track A: Filtration and Closed Systems |
| Alte Stuttgarter Reithalle |

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.

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

| 15:50 – 16:15 |
| PUPSIT in the Revised Annex I – Friend or Foe of the Pharmaceutical Entrepreneur? |
| Alte Stuttgarter Reithalle |

**Presenter:** Manuel Grund Process Engineer Roche Pharmaceuticals

| 16:15 – 16:40 |
15:50 – 17:10

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

15:50 – 16:15

Implementing Annex 1 Guidelines: A Comprehensive Approach to Sterility Assurance for Indirect Product Contact Parts

Presenter: Christian Rust B.S. Chemical and Biomolecular Engineering Technical Operations MSD

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 B.S. Chemical and Biomolecular Engineering Technical Operations MSD

Panelist: Helen Sauter Dr Director Quality Assurance Vetter Pharma Fertigung GmbH & Co. KG
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 learn 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

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<td>Total Particle Count – Tubing Qualification at GSK: Lessons Learned</td>
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<td><strong>Co-Presenter:</strong> Kurt Jaecques MA Global Aseptic Technologies Lead Monitoring &amp; Control GSK</td>
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<td><strong>Presenter:</strong> Andrew Gravett Principal Scientist Microbiology AstraZeneca</td>
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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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<td>Annex 1 and 'Good Technology Practice' - Interpretation and Engineering for This Side of Production</td>
<td>Johannes M. Rauschnabel PhD Director Advanced Technology Development and Innovation</td>
<td>Syntegon Technology GmbH</td>
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<td>09:20 – 09:40</td>
<td>Critical Factors in the Material Transfer Process</td>
<td>Anna Campanella PhD Global Aseptic Processing &amp; Sterility Assurance Lead</td>
<td>Takeda Pharmaceuticals International AG</td>
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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

**11:00 – 11:25**

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

**Presenter: Amanda McFarland MS** Senior Consultant *ValSource, Inc.*

**11:25 – 11:50**

Using Risk Management to Design Aseptic Process Simulations
Alte Stuttgart Reithalle

**Presenter: Alberto Gonzalez** Global Sterility Assurance Associate Director *Takeda*

**11:50 – 12:20**

Q&A, Discussion
Alte Stuttgart Reithalle

**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*

**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 MSc** Technology Lead *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 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 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**
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*

14:50 – 15:15

Remote presentation title to be announced

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

15:15 – 15:40

Remote presentation 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**
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*

16:30 – 16:35
Closing Remarks & Farewell
Alte Stuttgarter Reithalle

Committee: Falk Klar PhD PDA Europe