



Agenda

PDA Good Aseptic Manufacturing Conference 2025

Thursday, 22 May

09:00 – 09:10

Welcome and Introduction

Committee: Falk Klar, PhD, General Manager, Vice President Europe, *Parenteral Drug Association*

09:10 – 09:20

Welcome from the Co-Chairs

Co-Chair: Simone Biel, PhD, Senior Regulatory Consultant, *Merck KGaA*

Co-Chair: David Keen, MRSB CBiol, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*

09:20 – 10:35

Opening Plenary Part I

09:20 – 09:45

Title to be announced

Presenter: Alina Gruber

09:45 – 10:10

Title to be announced

10:10 – 10:35

Advancing Aseptic Fill & Finish: A Collaborative Breakthrough in Next-Generation Production

Co-Presenter: Markus Heinz, MSC, Strategy and Global Product Management, *Syntegon Technology GmbH*

Co-Presenter: Claudio Lazzati, MSc, Senior Manager, Equipment Engineering, *Pfizer*

10:35 – 11:05

Networking Coffee Break, Exhibition

11:05 – 12:20

Opening Plenary Part II

11:05 – 11:30

A holistic approach to addressing value chain emissions



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Presenter: Alissa Monk, Head of Sustainability, *ten23 health*

12:20 – 13:20

Networking Lunch Break, Poster Session, Exhibition

13:20 – 13:50

Guided Poster Walk

13:50 – 14:55

Session 1 Track A Closed Systems

Moderator: Christina Meissner, PhD, Group Manager, *AGES - Austrian Agency for Health and Food Safety GmbH*

13:50 – 14:00

A Risk-based Approach for Assuring the Integrity of Closed, Single-use Systems in Aseptic Processing

Presenter: William Peterson, Director, Global QA, *Merck & Co., Inc.*

14:00 – 14:10

Integrity Assurance of Final Sterile Filtration Process Step with SUS

Presenter: Nicola Rutigliani

14:10 – 14:20

Case Study of Aseptic Processing in a Closed System in Clean Room Class C

Presenter: Hauke Fender, PhD, QA Expert Aseptic, *BioNTech Innovation and Services Marburg GmbH*

14:20 – 14:55

Q&A, Discussion

Moderator: Christina Meissner, PhD, Group Manager, *AGES - Austrian Agency for Health and Food Safety GmbH*

Panelist: William Peterson, Director, Global QA, *Merck & Co., Inc.*

Panelist: Nicola Rutigliani

Panelist: Hauke Fender, PhD, QA Expert Aseptic, *BioNTech Innovation and Services Marburg GmbH*

13:50 – 14:55



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Session 1 Track B Enablers for Aseptic Manufacturing

Moderator: Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

13:50 – 14:00

Replace Settle Plates with Continuous Active Air Monitoring inside a production isolator

Presenter: Jules Moussatoff, PharmD, Head of Sterility Assurance, *Takeda*

14:00 – 14:10

Revision of Technical Report No. 33 Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods

Presenter: David Roesti

14:10 – 14:20

The Digital Transformation of Sterility Testing- The Case for Alternative Microbiological Methods with Complex Product Formulations

Presenter: Jonathan W. Kallay, Scientific Portfolio Specialist, *Charles River Laboratories*

14:20 – 14:55

Q&A, Discussion

Moderator: Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

Panelist: Jonathan W. Kallay, Scientific Portfolio Specialist, *Charles River Laboratories*

Panelist: Jules Moussatoff, PharmD, Head of Sterility Assurance, *Takeda*

Panelist: David Roesti

14:55 – 15:25

Networking Coffee Break & Exhibition

15:25 – 17:45

Session 2 Track A First Air

Moderator: Helen Sauter, Dr. Director Quality Assurance, *Vetter Pharma Fertigung GmbH & Co. KG*

15:25 – 15:50

Title to be announced

15:50 – 16:15



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Latest Technologies to Follow First-Air Principles According to Annex 1

Presenter: Patrick Wieland

16:15 – 17:45

Q&A, Discussion

Moderator: Helen Sauter, Dr, Director Quality Assurance, *Vetter Pharma Fertigung GmbH & Co. KG*

Panelist: Patrick Wieland

15:25 – 17:45

Session 2 Track B Decontamination

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

15:25 – 15:50

Application and Qualification of an Automated UV Disinfection Robot for Aseptic Cleanrooms

Co-Presenter: Andrew Gravett, Principal Scientist Microbiology, *AstraZeneca*

Co-Presenter: Vincent Hamers, Site Microbiologist / Development Quality Biologics Microbiologist, *AstraZeneca*

15:50 – 16:15

Case Study: E-Beam Used More Than 15 Years as Transfer Technology for RTU Pre-Filled Syringes at Pfizer Grange Castle Ireland on Multiple Filling Lines

Co-Presenter: David Kelly, MEng, BEng, HDip, Manager, Global Engineering, *Pfizer Inc*

Co-Presenter: Manfred Holzer, Strategic Product Manager E-Beam Technology, *SKAN AG*

16:15 – 17:45

Q&A, Discussion

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

Panelist: Andrew Gravett, Principal Scientist Microbiology, *AstraZeneca*

Panelist: Vincent Hamers, Site Microbiologist / Development Quality Biologics Microbiologist, *AstraZeneca*

Panelist: David Kelly, MEng, BEng, HDip, Manager, Global Engineering, *Pfizer Inc*

Panelist: Manfred Holzer, Strategic Product Manager E-Beam Technology, *SKAN AG*

17:45 – 17:45



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End of Conference Day 1 & Networking Event

Friday, 23 May

09:00 – 10:10

Session 3 Track A Aseptic Process Simulation

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

09:00 – 09:20

EU GMP Annex 1, QRM & APS: Practical Approach & Points to Consider

Presenter: Morcos Mikhail Fahmy Loka, MBA, CMQ/OE, CQA, CPGP, CPIP, Quality Senior Manager Biologics F&F and New Projects, *Minapharm*

09:20 – 09:40

Aseptic Process Simulation: Pragmatic and Innovative Approach

Co-Presenter: Isabelle Hoenen, PharmD, Senior Advisor Quality for Sterility Assurance, *Lilly France SAS*

Co-Presenter: Jerome Weiss

09:40 – 10:10

Q&A, Discussion

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

Panelist: Morcos Mikhail Fahmy Loka, MBA, CMQ/OE, CQA, CPGP, CPIP, Quality Senior Manager Biologics F&F and New Projects, *Minapharm*

Panelist: Isabelle Hoenen, PharmD, Senior Advisor Quality for Sterility Assurance, *Lilly France SAS*

Panelist: Jerome Weiss

09:00 – 10:10

Session 3 Track B Particle Risk Mitigation

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

09:00 – 09:20

Total Particle Count: two options to be compliant to Annex 1: 3-way valve redesign, Counter resistant to VHP

Presenter: Paul Devuyt, Master Bioengineer, Senior Manager Aseptic Technologies, *GSK*

09:20 – 09:40



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Achieving Particle Reduction via Supplier Annex 1 Strategies and Innovation in RTU / RTF Packaging

Presenter: Colleen O'Brien, MS, Strategy and Technical Affairs, *Gerresheimer*

09:40 – 10:10

Q&A, Discussion

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

Panelist: Paul Devuyst, Master Bioengineer, Senior Manager Aseptic Technologies, *GSK*

Panelist: Colleen O'Brien, MS, Strategy and Technical Affairs, *Gerresheimer*

10:10 – 10:40

Networking Coffee Break, Poster Session & Exhibition

10:40 – 11:50

Session 4 Track A Excellence in Manufacturing Execution

Moderator: Klaus Ullherr, Senior Product Manager, *Syntegon Technology GmbH*

10:40 – 11:50

Session 4 Track B Application of Quality Risk Management

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

10:40 – 11:00

Human Error Investigation and Reduction

Presenter: Ginette Collazo

11:00 – 11:20

Title to be announced

Presenter: Brian Thome, PhD, Head, External Biologics and Gene Therapy Manufacturing Sciences, *Biogen*

11:20 – 11:50

Q&A, Discussion

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

Panelist: Brian Thome, PhD, Head, External Biologics and Gene Therapy Manufacturing Sciences, *Biogen*



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11:50 – 12:50

Networking Lunch Break, Poster Session & Exhibition

12:50 – 14:30

Closing Plenary Part I

12:50 – 13:00

Interactive Questionnaire Session

13:00 – 13:20

Title to be announced

13:20 – 13:45

Title to be announced

13:45 – 14:30

Plenary Discussion

14:30 – 15:00

Networking Coffee Break, Poster Session & Exhibition

15:00 – 03:05

Raffle Card Announcement

15:05 – 15:10

Best Poster Presentation

15:10 – 16:10

Closing Plenary Part II

15:10 – 16:10

Interactive Round Table Session



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16:10 – 16:20

Co-Chairs Conference Summary

Co-Chair: Simone Biel, PhD, Senior Regulatory Consultant, *Merck KGaA*

Co-Chair: David Keen, MRSB CBiol, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*

16:20 – 16:25

Closing Remarks & Farewell

Presenter: Falk Klar, PhD, General Manager, Vice President Europe, *Parenteral Drug Association*