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

What is the future of aseptic manufacturing? What is the benefit? In this session we will be hearing from the frontlines of healthcare providers and our regulators who will be talking about the impact of aseptic medicines and how the reverberations of regulatory changes are being felt. The session will be finished by a quick fire round of three companies who are working at the cutting edge of our industry, with a view to what is happening in the future.

Moderator: David Keen, **MRSB CBiol**, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*

09:20 – 09:45

From Good Manufacturing to Good Use of Treatments

Presenter: Alina Gruber

09:45 – 10:10

The new Annex 1: source of challenges and driver of innovation – an agency perspective

Regulatory Presenter: Paula Walser, **Doctorate in Chemistry**, Head of GMDP Inspection Operations, *Swissmedic*

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: Raquel Casañ Crespo, **MSc**, Project Manager, *Novo Nordisk A/S*

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10:35 – 11:05

Networking Coffee Break, Exhibition

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11:05 – 12:20

Opening Plenary Part II

Moderator: David Keen, **MRSB CBiol**, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*

11:05 – 11:30

A Holistic Approach to Addressing Value Chain Emissions

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

11:30 – 11:40

Interactive Questionnaire Session

Moderator: David Keen, **MRSB CBiol**, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*

Moderator:

Moderator:

11:40 – 12:20

Plenary Discussion

Moderator: David Keen, **MRSB CBiol**, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*

Panelist: Alina Gruber

Panelist: Paula Walser, **Doctorate in Chemistry**, Head of GMDP Inspection Operations, *Swissmedic*

Panelist: Raquel Casañ Crespo, **MSc**, Project Manager, *Novo Nordisk A/S*

Panelist: Markus Heinz, **MSC**, Strategy and Global Product Management , *Syntegon Technology GmbH*

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

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12:20 – 12:50

Guided Poster Walk

12:30 – 13:50

Networking Lunch Break, Poster Session, Exhibition

13:50 – 14:55

Session 1 Track A Closed Systems

At heart of patient safety, the Annex 1 requires closed systems to be shown integral at every usage when being used in a lower classified area than grade A. However, how integral is integral enough to prevent contamination risk to the sterile product? In this session, experts will present cases applying risk-based approaches to assess whether a point-of-use integrity testing of a closed SUS is required and if yes, how the integrity testing can be achieved. The cases presented here include aseptic processing in final sterilizing filtration as well as aseptic formulation and sterile drug substance processes. The experts will assess and discuss the regulatory expectations and implications on patient safety as well as measures that should be taken to ensure proper compliance.

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: Christian Scarpato, Production Support Manager, *Merck*

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*

Moderator: Yuan-An Liu, **PhD**, Associate Director CMC, *BioNTech SE*

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

Panelist: Christian Scarpato, Production Support Manager, *Merck*

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

13:50 – 14:55

Session 1 Track B Enablers for Aseptic Manufacturing

EU GMP Annex 1 mentions in Chapter 2 Principles the use of rapid/alternative methods as well as continuous monitoring systems—key enablers for new approaches in aseptic manufacturing. During the speed talk session, alternative methods for microbiological monitoring and digital transformation will be introduced, followed by a Q&A session. Learn how modern methods enable faster reactions and provide real-time results.

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*

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14:00 – 14:10

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

Presenter: David Roesti, **PhD**, Senior Technical Steward, *Novartis Pharma Stein AG*

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, **PhD**, Senior Technical Steward, *Novartis Pharma Stein AG*

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

Presenter: Tarik Cheema, **PhD**, Process Unit Lead DP (GEF) , *F. Hoffmann-La Roche AG*

15:50 – 16:15

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

Presenter: Patrick Wieland, **MA**, Global Director Business Development, *Bausch+Ströbel SE + Co. KG*

16:15 – 17:45

Q&A, Discussion

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

Panelist: Tarik Cheema, **PhD**, Process Unit Lead DP (GEF) , *F. Hoffmann-La Roche AG*

Panelist: Patrick Wieland, **MA**, Global Director Business Development, *Bausch+Ströbel SE + Co. KG*

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

End of Conference Day 1 & Networking Event

Friday, 23 May

09:00 – 10:10

Agenda

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Session 3 Track A Aseptic Process Simulation

Moderator: Tarik Cheema, **PhD**, Process Unit Lead DP (GEF) , *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 Approach for Key Topics

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**, Process Unit Lead DP (GEF) , *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

The minimization of particle contamination as well as monitoring systems using reliable particle counting are fundamental to guarantee an effective Contamination Control Strategy (CCS). In this session, you will explore recommendations regarding how to address compliance with regulations and the requirement of the revised EU GMP Annex 1 on non-viable Particle Counting systems and which types of improvements are provided by Ready to Use/Ready to Fill primary packaging suppliers to support customers in achieving particle reduction.

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 Annex1: 3-way valve redesign, Counter resistant to VHP

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

09:20 – 09:40

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

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

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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. Makowenskyj, **MEng**, Senior Director of Design Consulting, *G-CON*

10:40 – 11:00

Applying QRM and QbD Principles to Fill-Finish Equipment: A Scientific Approach to Measure Risk Reduction

Co-Presenter: Julian Petersen, **BEng**, Head of Business Development Pharma , *Groninger*

Co-Presenter: Sebastian Scheler, **MSc**, Managing Director, *Innerspace*

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. Makowenskyj, **MEng**, Senior Director of Design Consulting, *G-CON*

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

Panelist: Julian Petersen, **BEng**, Head of Business Development Pharma , *Groninger*

Panelist: Sebastian Scheler, **MSc**, Managing Director, *Innerspace*

11:50 – 12:50

Networking Lunch Break, Poster Session & Exhibition

12:50 – 13:05

Award Ceremony

13:05 – 14:30

Closing Plenary Part I

As we conclude the conference, join us for a dynamic session to gain insights into the importance of data-driven approaches in ensuring compliance and quality in sterile environments, alongside understanding how Nudge Theory can influence better decision-making among teams - despite advances in AI, machine learning, and robotics that enhance safety, the critical risk factor remains people. Additionally, the session will highlight the pivotal role of the World Health Organization in unlocking pharmaceutical opportunities across Africa, fostering growth and innovation in the region. This session promises to inspire collaboration and forward-thinking as we reflect on the key takeaways from the conference and explore the path ahead for the industry.

Moderator: Simone Biel, **PhD**, Senior Regulatory Consultant, *Merck KGaA*

13:05 – 13:15

Interactive Questionnaire Session

13:15 – 13:40

Regulatory Expectations on Data-Driven Sterile Manufacturing

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

13:40 – 14:00

Nudge Theory: What Is It and How People Can Be Influenced to Make Better Decisions in Aseptic Manufacturing

Presenter: David Keen, **MRSB CBiol**, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*

14:00 – 14:45

Plenary Discussion

Moderator: Simone Biel, **PhD**, Senior Regulatory Consultant, *Merck KGaA*

14:45 – 15:15

Networking Coffee Break, Poster Session & Exhibition

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15:15 – 15:20

Raffle Card Announcement

15:20 – 15:25

Best Poster Presentation

15:25 – 16:25

Closing Plenary Part II

Moderator: Simone Biel, PhD, Senior Regulatory Consultant, *Merck KGaA*

> 15:25 – 16:25
>
> Interactive Round Table Session

16:25 – 16:35

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*

16:35 – 16:40

Closing Remarks & Farewell

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