Agenda

PDA Good Aseptic Manufacturing Conference 2024

Wednesday, 15 May

08:00 – 17:30

Registration Open
Saal MARITIM & Lobby Empore

09:00 – 09:05

Welcome and Introduction
Alte Stuttgarter Reithalle

Committee Member: Falk Klar, **PhD**, *Parenteral Drug Association*

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 EU GMP 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

Keynote: Empowering Patients Through Good Aseptic Manufacturing: A Vital Journey Towards Safer Medical Products

Presenter: Hussain Jafri, **PhD**, Executive Director , *World Patients Alliance*

09:45 – 10:15

Fit for Future: Sterile Manufacture? A Personal View on Revised EU GMP Annex 1

Regulatory Presenter: Daniel Mueller, **PhD**, Head of GMDP-Inspectorate, *Regierungspraesidium Tuebingen, Germany*

10:15 – 10:45

Implementation of EU GMP Annex 1 – Inspection Experiences and Expectations

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

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10:45 – 11:15

Networking Coffee Break, Poster Session & Exhibition

Saal MARITIM & Lobby Empore

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

The Evolution of the Contamination Control Strategy from Concept/Conversion to Continuous Improvement

Presenter: Tracy Moore, Director, *TM Pharma Group Ltd*

11:35 – 11:55

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

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

11:55 – 12:00

Interactive Questionnaire Session

12:00 – 12:45

Plenary Discussion

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*

Panelist: Christina Meissner, *AGES - Austrian Agency for Health and Food Safety*

Panelist: Daniel Mueller, **PhD**, Head of GMDP-Inspectorate, *Regierungspraesidium Tuebingen, Germany*

Panelist: Marisa Delbo, **PharmD**, Consultant , *NA*

12:45 – 14:00

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PDA Good Aseptic Manufacturing Conference 2024

Networking Lunch Break & Exhibition

Saal MARITIM & Lobby Empore

13:30 – 14:00

Guided Poster Walk

Lobby Empore

13:30 – 14:00

Biodecontamination of Raw Materials in Packaging Production Process

Poster Presenter: Andrea Weiss

13:30 – 14:00

CFD - Computational Fluid Dynamics for Airflow Visualization Studies

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

13:30 – 14:00

eBeam Technology – Transfer Technology for Pre-Sterilized RTU Components

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

13:30 – 14:00

Environmental Monitoring in LIMS

Poster Presenter: Julia Wiesner, **PhD**, Senior Director, Head of QC & QA Systems, *Merz Pharma GmbH & Co. KGaA*

13:30 – 14:00

Far UV-C Light - Safe and Effective Decontamination

Poster Presenter: Peter Tonning

13:30 – 14:00

Headspace Analysis as Innovative Method for Media Fill Inspection

Poster Presenter: Michael Mettraux, **MSc ETH**, Development Engineer, *WILCO AG*

13:30 – 14:00

Particle Loss in Transport Tubing: How to Address the New Annex 1 Requirement

Poster Presenter: Serena Steidl, **MD**, EMEA Advisory Project Coordinator - Advisory Specialist , *Particle Measuring Systems*

13:30 – 14:00

Rapid Sterility Testing as the Critical and Final Result for Product Release - Design Verification (DV) Data

Poster Presenter: Johannes Oberdörfer, **B.Sc**, Field Application Scientist, *Rapid Micro Biosystems*

13:30 – 14:00

Reducing Glove Intervention in Fill & Finish Process

Poster Presenter: Patrick Wieland

13:30 – 14:00

The Need for High Quality in Primary Packaging

Poster Presenter: Ana Kuschel, **PhD**, Principal Scientific Affairs, *West Pharmaceutical Services, Inc.*

Poster Presenter: Niamh Bissett

13:30 – 14:00

Trending and Pattern Recognition for Annex1

Poster Presenter: Susan B. Cleary, **B.CS, EMBA**, Director Product Development, *Novatek*

13:30 – 14:00

VHP Uptake of Manufacturing Tubing Used for Aseptic Fill-Finish Processes of Biopharmaceutical Drug Products

Poster Presenter: Dilara Ali, **MSc**, PhD Student , *ten23 health*

14:00 – 15:20

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

Alte Stuttgarter Reithalle

The new EU GMP Annex 1 introduces new requirements relating to the entire freeze-drying process including product transfer. Now you can dive into the main aspects of the new requirements by analyzing 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 concerning 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 a simulation of lyophilization justified by a 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 EU GMP Annex 1

Regulatory Presenter: Marisa Delbo, **PharmD**, Consultant , *NA*

14:25 – 14:50

A Better Approach to Aseptic Process Simulation (APS) for Lyophilized Products - APS Approach for Freeze-Drying Process Considering EU GMP 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, *Stevanato Group*

Panelist: Marisa Delbo, **PharmD**, Consultant , *NA*

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

14:00 – 15:20

Session 1, Track B: Sustainability in Aseptic Manufacturing

Salon Köln, Bonn, Hamburg

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. Water for Injection (WFI), Steam generation, HVAC, circular economy (Single use and Take-back program). Then focus will be given to Big Data and Artificial intelligence (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

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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 the 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 that 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 EU GMP Annex I – Friend or Foe of the Pharmaceutical Entrepreneur?

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

16:15 – 16:40

Contamination Control Strategies in Processing of Frozen Sterile Bulk Drug Product in Single-use Bag Assembly

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

16:40 – 17:10

Q&A, Discussion

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

Panelist: Manuel Grund, Process Engineer, *Roche Pharmaceuticals*

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

15:50 – 17:10

Session 2, Track B: Aseptic Set-Up of Filling Machines

Salon Köln, Bonn, Hamburg

With the requirements of the new EU GMP Annex 1, the aseptic set-up of a filling machine gets 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 newly developed machine with a gloveless isolator. Where you do 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 use pre-sterilized single-use filling systems.

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

15:50 – 16:15

Implementing EU GMP 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 EU GMP 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*

17:10 – 22:00

End of Conference Day 1 & Networking Event

Thursday, 16 May

08:00 – 17:45

Registration Open

Saal MARITIM & Lobby Empore

09:00 – 10:30

Session 3, Track A: Environmental Monitoring

Alte Stuttgarter Reithalle

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, lessons 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 Environmental Monitoring, 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

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

Co-Presenter: Kurt Jaecques, **MA**, Global Aseptic Technologies Lead Monitoring & Control, *GSK*

09:20 – 09:40

How to Collect All Environmental Monitoring Data and Doing Computerized Trending Without Entering the Data Manually

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

Co-Presenter: Susan B. Cleary, **B.CS, EMBA**, Director Product Development, *Novatek*

09:40 – 10:00

Automated Reading of Agar Plates Using AI and Machine Learning

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

10:00 – 10:30

Q&A, Discussion

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*

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

Panelist: Susan B. Cleary, **B.CS, EMBA**, Director Product Development, *Novatek*

09:00 – 10:30

Session 3, Track B: Equipment for Aseptic Processes

Salon Köln, Bonn, Hamburg

During this session, we will explore the technological advancements that could enhance existing production lines and address specific material transfer needs to minimize particulates, pyro, and bioburden. The speakers will delve into strategies for aligning practices with the Annex requirements. We will discuss how leveraging technology can enhance aseptic environments and share insights on retrofitting equipment and processes to meet material transfer and sanitization standards. Our approach will break down these complex concepts into manageable steps that can be seamlessly integrated into your operations.

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

09:00 – 09:20

EU GMP 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

Disinfection and Material Intake Programs – Implementation, Challenges and Solutions

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: RABS/Isolator

Alte Stuttgarter Reithalle

People, what they carry, and their actions are the major source of microbial contamination in aseptic operations. Isolator technology is a great way of preventing people from directly accessing critical areas. A perceived weak point in isolators can be the gloves, should they fail. Gloveless isolators take that control a step further by eliminating the need for people in the most critical of areas. Cleaning and disinfection has always been a principle control point for mitigating the risk of microbial contamination from people. Automating the disinfection process further reduces the risk by ensuring human error is controlled or even eliminated. Join us in these two talks to further understand how the latest technologies can help improve the quality of aseptic products and the environments we manufacture them.

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

11:00 – 11:25

Pre-Validation of a Gloveless Isolator Filling Line - Experience and Lessons Learned

Presenter: Bianca Bohrer, **Dipl Ing**, Managing Director, *PSM GmbH*

11:25 – 11:50

Leveraging Emerging Technologies for H2O2 Bio-Decontamination: From Novel Process Data to Real Process Impact

Presenter: Martin Novak, **MSc**, Technology Lead, *SKAN AG*

11:50 – 12:20

Q&A, Discussion

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

Panelist: Bianca Bohrer, **Dipl Ing**, Managing Director, *PSM GmbH*

Panelist: Martin Novak, **MSc**, Technology Lead, *SKAN AG*

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11:00 – 12:20

Session 4, Track B: Quality Risk Management

Salon Köln, Bonn, Hamburg

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

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

11:25 – 11:50

Using Risk Management to Design Aseptic Process Simulations

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.*

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*

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PDA Good Aseptic Manufacturing Conference 2024

13:30 – 13:40

Excitement @Syntegon – Insights and Preparation for the Syntegon Factory Tour

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

13:40 – 13:55

Introduction of PDA Points to Consider (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, **BSc Hons PGDip**, 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, *Parenteral Drug Association*

14:50 – 16:20

Closing Plenary Part II

Alte Stuttgarter Reithalle

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

14:50 – 15:15

A Review of Recent Inspectional Trends: Aseptic Manufacturing - remote presentation -

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

15:15 – 15:40

Updates on EU GMP Annex 1 - remote presentation -

Regulatory Presenter: Roberto Conocchia, **MD**, GMP Technical Lead, *European Medicine Agency*

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15:40 – 16:20

Plenary 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, **BSc Hons PGDip**, Director, Operation Quality QA Audit and Compliance, *AbbVie Inc.*

Panelist: Roberto Conocchia, **MD**, GMP Technical Lead, *European Medicine Agency*

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

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

Panelist: Christina Meissner, *AGES - Austrian Agency for Health and Food Safety*

Panelist: Marisa Delbo, **PharmD**, Consultant , *NA*

Panelist: Daniel Mueller, **PhD**, Head of GMDP-Inspectorate, *Regierungspraesidium Tuebingen, Germany*

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 Member: Falk Klar, **PhD**, *Parenteral Drug Association*