2023 PDA

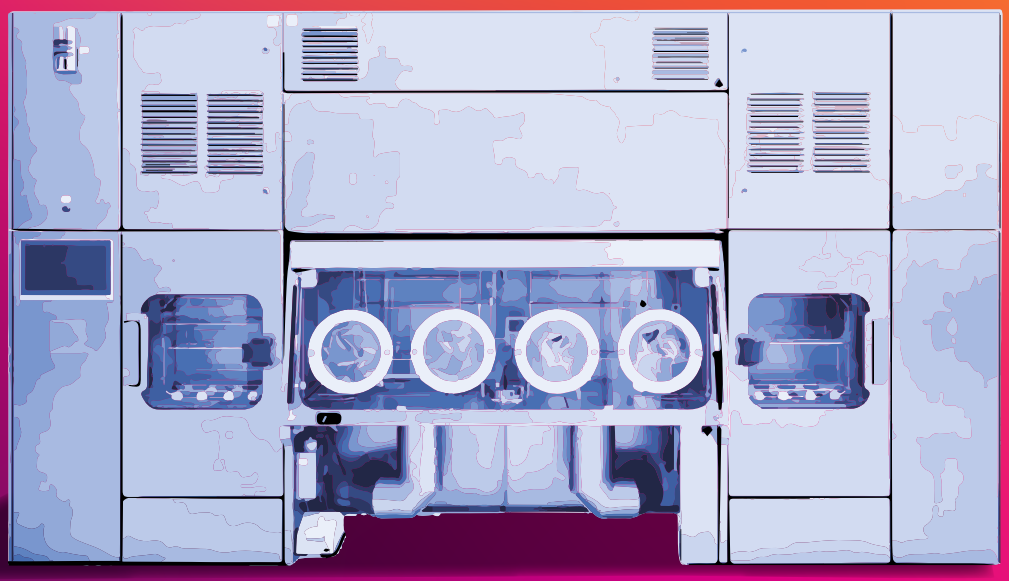
GOOD ASEPTIC MANUFACTURING CONFERENCE

pda.org/EU/GoodAseptic2023

23-24 MAY 2023
LEIPZIG, GERMANY
EXHIBITION: 23-24 MAY 2023
SITE VISIT AT IDT BIOLOGIKA: 25 MAY 2023

CALL FOR ABSTRACTS

ABSTRACT SUBMISSION DEADLINE:
11 NOVEMBER 2022



CONNECTING PEOPLE SCIENCE AND REGULATION®

WELCOME FROM THE CHAIRS

Dear Colleagues,

The **2023 PDA Good Aseptic Manufacturing Conference** will take place on **23-24 May 2023 in Leipzig, Germany.**

We are pleased to announce that we will co-chair this face-to-face event. The new EU GMP Annex 1 is now officially published and to take effect in August 2023. One of the most important new requirements is the implementation of a contamination control strategy. Furthermore, decisions and processes should have their rationale in a risk-based approach. The revised EU GMP Annex 1 will be the core of our conference. We are happy to invite you to submit a paper or poster abstract to present on your novel approaches and/or ongoing challenges.

It will be a great occasion to share efficient and sustainable solutions in implementing the requirements of EU GMP Annex 1, including new methods, innovation tools, and developments covering new technologies, equipment, and utilities. Abstracts must be non-commercial in nature, describing new developments or challenges and solutions that significantly contribute to the body of knowledge relating to Aseptic Manufacturing. The Scientific Program Planning Committee will review all proposals carefully and consider podium and poster contributions.

We look forward to receiving your topic proposals and we very much hope to meet you in Leipzig next year.

Sincerely,
The Chairs

Kerstin Wilken,
IDT Biologika

Paul Devuyst,
GSK

CALL FOR ABSTRACTS

TOPICS AREAS OF INTEREST WILL INCLUDE

1. PHARMACEUTICAL QUALITY SYSTEM

- Quality Risk Management
- Role of Quality Assurance Department/Personnel
- Continuous Improvement
- Management of Non-Conformities
- Expectations of Regulators/Inspectors

2. CONTAMINATION CONTROL STRATEGY (CCS)

- Microbial Quality Control Strategy
- Process Knowledge
- Necessary Elements of CCS
- Integration of CCS in Pharmaceutical Quality System
- In-Process Controls
- Root Cause Investigation & Determination
- Trending
- Corrective and Preventive Actions

3. PREMISES AND BARRIER SYSTEMS

- Cleanroom Design
- Restricted Access Barrier Systems, Isolators
- VHP Cycle Development and Validation
- Air Flow Visualization
- Glove Integrity
- Gloveless Isolator
- Application of EN ISO 14644
- Cleanroom Classification
- Cleanroom Qualification
- Pressure Differences
- Airlocks
- Heating, Ventilation, and Air Conditioning System
- Retrofitting of Existing Installations versus New Installations

4. EQUIPMENT AND UTILITIES

- Robotics
- Automation
- Transfer of Material, Equipment, Components
- Cleaning & Disinfection
- Decontamination
- Advantages and Limitations of Vaporized Hydrogen Peroxide
- Sterilization
- Water System
- Steam
- Gases and Vacuum System
- Heating/Cooling and Hydraulic System

5. PERSONNEL

- Qualification and Training
- Personnel Monitoring
- Transfer of Personnel
- Determination of Number of Personnel
- Gowning
- Access Limitations/ Disqualification
- Personal Hygiene
- How Operators can Support CCS

22. Sep 2022

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Kerstin Wilken, *IDT Biologika (Chair)*
Paul Devuyst, *GSK (Chair)*
Darren Beckett, *Sterility Solutions*
Simone Biel, *Merck*
Richard Denk, *SKAN*
Rainer Glöckler, *Swissfillion*
Gabriele Gori, *Thermo Fisher*
Rob Hendrix, *Janssen Pharma*
David Keen, *Ecolab*
Arne Kloke, *Alliance to Zero on behalf of SCHOTT Pharma*
Peter Makowenskyj, *GCon Bio*
Tracy Moore, *TM Pharma Group*
Andrea Salmaso, *Stevanato Group*
Helen Sauter, *Vetter Pharma*
Carrie Horton, *PDA*
Falk Klar, *PDA Europe*
Caroline Lynar, *Junior Manager Programs & Events, PDA Europe*

VENUE

LEIPZIG MARRIOTT HOTEL

Am Hallischen Tor 1, 04109 Leipzig, Germany
Tel: +49 341-9653-0 | https://bit.ly/3DHZ6Ts

BUT ARE NOT LIMITED TO THE FOLLOWING

6. ENVIRONMENTAL MONITORING AND QUALITY CONTROL

- Rapid Micro Methods
- Bioburden Test
- Sterility Test
- Trend Data
- Viable/Nonviable Particles
- Quality Control of Small Batch Sizes
- Enzymatic/Biological Indicators

7. ASEPTIC PROCESS SIMULATION (APS)

- Aseptic Manipulations/Interventions
- Process Simulation Test Plan
- Worst Case Conditions
- Batch Size/Sample Size Considerations
- Bracketing Approach
- Determination of Number of APS for Successful Validation
- Parameters for Successful Validation
- APS for Small Scale Batches

8. MANUFACTURING

- Filtration
- Filter Integrity/PUPSIT
- Container Closure Systems/ Container Closure Integrity
- Aseptic Connections
- Closed Systems
- Single-Use-Systems
- Bio-Safety
- Lyophilization
- Blow-Fill-Seal/Form-Fill-Seal
- Quality on the Shop Floor/ Quality Oversight
- Shortages in Critical Raw Materials
- Shortages in Packaging Material
- Cost Increase in Energy, Water, Supply Materials
- Price Negotiation and Economical Challenges

9. PARTNERING AND COOPERATION IN ASEPTIC MANUFACTURING

- Relationship CDMO & Contract Giver
- Quality Systems Including Quality Agreements
- Project Management in Outsourcing
- Sourcing/Selection of CDMOs
- Technology Transfer (Manufacturing Process/ Analytical Testing)
- Health Safety & Environment
- From Product to Solution
- Expectations for Suppliers not Working under GMP Regulation
- Defining Responsibilities to Comply with the Regulation

10. SUSTAINABILITY

- Ecodesign Guidelines for Machinery and Cleanrooms
- Eco-Balancing of Products and Processes
- Life Cycle Assessment (LCA) Calculations
- Disposal Practices – Today and Tomorrow
- Packaging Design and Material Selection
- Water, Waste, and Energy Reduction Programs (Equipment and Infrastructure)
- Reduction of Wastewater
- Equipment and Process Design for Material Waste Separation/ Sorting
- Reverse Manufacturing Lines/ Disassembly
- Material/ Value Recovery of Equipment after Use/at the End-of-Life
- Measures for Equipment Lifetime Elongation
- Circular Economy
- Sterilization Impacts
- Design of Facilities/Installation to Support Saving Resources

SUBMISSION PROCESS

DEADLINE: 11 NOV 2022

All submitted abstracts will be reviewed by the Scientific Program Planning Committee for acceptance. PDA Europe will provide a complimentary registration per on-site podium presentation. Additional on-site presenters and on-site poster presenters are required to pay appropriate conference registration fees. Abstracts not selected for a podium presentation may be invited to join as a scientific poster contribution.

THE ONLINE PROCESS ASKS YOU TO PROVIDE THE FOLLOWING INFORMATION:

- PRESENTATION TITLE
- PRESENTER'S NAME AND CONTACT DETAILS
- PRESENTER'S BIOGRAPHY (APPROX. 100 WORDS)
- ADDITIONAL SPEAKERS (IF APPLICABLE)
- KEY OBJECTIVES OF TOPIC
- 2-3 PARAGRAPH ABSTRACT, SUMMARIZING THE TOPIC

Please click or scan the QR Code to submit your abstract.

https://bit.ly/3DE0hTF

If you have any further questions, please do not hesitate to contact programs-europe@pda.org

TO EXHIBIT: PDA is seeking vendors who provide products/services in support of this conference. Space on-site is limited and is on a first-come, first-serve basis. To reserve your space, please contact Christopher Haertig at **expo-europe@pda.org.**

DEADLINE: 07 APR 2023

To join our scientific poster session, the poster has to be non-commercial in nature. Please send a printable PDF file according to the following specifications:

Canvas Size to Work on:
85 cm x 120 cm (33,465 x 47,244 in) Portrait Format
Slug / Bleed: 2 mm (0,079 in)

Images:
120dpi (low) - 150dpi (high)
Depending on size.
All Images Color Profile
ISO Coated v2 (ECI)

Document size of the PDF:
85 cm x 206 cm
(33,465 x 81,102 in)
Portrait Format
Slug / Bleed: 2 mm (0,079 in)

ALL POSTERS WILL BE PRINTED BY PDA AND DISPLAYED AS PART OF THE EXHIBITION.

Please send your file and poster title to Christopher Haertig **expo-europe@pda.org.**

PDA EUROPE

CONFERENCES AND EVENTS

FOR FURTHER INFORMATION
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www.pda.org

2023

22. Sep 2022

18-19 APR 2023	2023 PDA Parenteral Packaging Conference	TBA
03-04 MAY 2023	2023 PDA Robotics and Automation Conference	TBA
23-24 MAY 2023	2023 PDA Good Aseptic Manufacturing Conference	Leipzig, Germany
20-21 JUN 2023	2023 PDA Virus Conference	TBA
12-13 SEP 2023	2023 PDA BioManufacturing Conference	TBA
17-18 OCT 2023	2023 PDA Universe of Pre-filled Syringes and Injection Devices Conference	Gothenburg, Sweden
07-08 NOV 2023	2023 PDA Quality and Regulations Conference	TBA