2024 PDA

GOOD ASEPTIC MANUFACTURING CONFERENCE

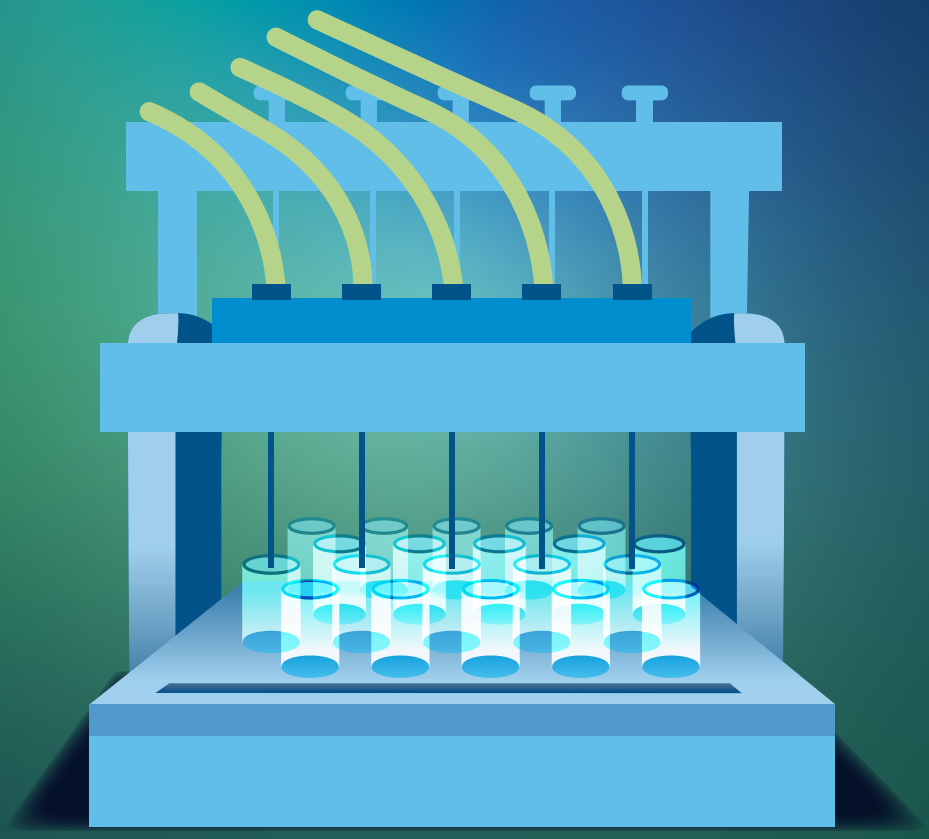
ASSESSING EU GMP ANNEX 1: 264 DAYS INTO THE JOURNEY

pda.org/EU/2024GAM

15-16 MAY 2024
STUTTGART, GERMANY
EXHIBITION: 15-16 MAY 2024
SITE VISIT AT SYNTEGON: 17 MAY 2024

CALL FOR ABSTRACTS

ABSTRACT SUBMISSION DEADLINE: 03 NOVEMBER 2023



CONNECTING PEOPLE SCIENCE AND REGULATION®

WELCOME FROM THE CO-CHAIRS

Dear Colleague,

We would like to warmly invite you to submit a paper or poster abstract for presentation for the **2024 PDA Good Aseptic Manufacturing Conference** which will take place on **15-16 May 2024** in Stuttgart, Germany.

Abstracts must be non-commercial in nature, describing new and innovative developments or work that significantly contributes to the body of knowledge relating to aseptic manufacturing and all related aspects as stated below.

The Scientific Program Planning Committee will review all proposals carefully and consider podium and poster contributions.

We look forward to receiving your topic proposal!

Sincerely,

The Co-Chairs

Simone Biel,
Merck

Darren Beckett,
Fedegari

CALL FOR ABSTRACTS

TOPICS AREAS OF INTEREST WILL INCLUDE

1. PHARMACEUTICAL QUALITY SYSTEM

- Shared Experiences After One Year of Revised EU GMP Annex 1
- Quality Risk Management
- Role of Quality Assurance Department/Personnel
- Continuous Improvement
- Management of Non-Conformities
- Expectations of Regulators/Inspectors
- Experience with National/ International Regulatory Inspections After Revised EU GMP Annex 1 Has Come Into Force
- Feedback by FDA, PIC/s, WHO, and Other Countries/Organizations/ Regulators

2. CONTAMINATION CONTROL STRATEGY (CCS)

- Quality Control Strategy (Microbial, Endotoxin/Pyrogens, Particles)
- Process Knowledge
- Case Studies of CCS Implementation
- Necessary Elements of CCS
- Integration of CCS in Pharmaceutical Quality System
- In-Process Controls
- Root Cause Investigation and Determination
- Trending
- Corrective and Preventive Actions
- Digital Tools

3. PREMISES AND BARRIER SYSTEMS

- Retrofitting of Existing Installations Versus New Installations
- Cleanroom Design
- Restricted Access Barrier Systems, Isolators
- Vaporized Hydrogen Peroxide Cycle Development and Validation
- Air Flow Visualization
- Glove Integrity
- Reduction of Glove Interventions on Existing Lines
- Gloveless Isolator
- Application of EN ISO 14644
- Cleanroom Classification/ Qualification
- Pressure Differences
- Airlocks
- Heating, Ventilation, and Air Conditioning System
- Facility Design

4. EQUIPMENT AND UTILITIES

- Robotics
- Automation
- Transfer of Material, Equipment, Components
- E-Beam and Material Airlock
- Cleaning and Disinfection
- Decontamination
- Cleaning Validation
- Case Studies on the Sterilization of Indirect Product Contact Parts
- 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/VR Training
- Personnel Monitoring
- Transfer of Personnel
- Determination of Number of Personnel
- Gowning
- Access Limitations/Disqualification
- Personal Hygiene
- How Your Operators Can Support CCS

Abstracts must be non-commercial in nature, describing new developments or work that significantly contributes to the body of knowledge relating to aseptic manufacturing. Case studies and current challenges are of special interest.

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Simone Biel, *Merck*
Darren Beckett, *Fedegari*
Richard Denk, *SKAN*
Paul Devuyst, *GSK*
Rainer Glöckler, *ten23 health*
Gabriele Gori, *Biogen*
David Keen, *Ecolab*
Peter Makowenskyj, *GCon Bio*
Christina Meissner, *AGES*
Tracy Moore, *TM Pharma Group*
Andrea Salmaso, *Stevanato Group*
Helen Sauter, *Vetter Pharma*
Klaus Ullherr, *Syntegon*
Jessie Lindner, *PDA*
Falk Klar, *PDA Europe*
Caroline Lynar, *Manager Programs & Events, PDA Europe*

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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 Aseptic Process Simulations for Successful Validation
- Parameters for Successful Validation
- APS for Small Scale Batches

8. MANUFACTURING

- Shortages in Critical Raw Materials/ Components/Products
- Shortages in Packaging Material
- Cost Increase in Energy, Water, Supply Materials
- Price Negotiation and Economical Challenges
- Affordability of Drug Products Versus Manufacturing Cost
- Patient Benefits Versus Manufacturing Cost
- Filtration/Filter Integrity/PUPSIT
- Container Closure Systems/ Container Closure Integrity
- Reducing Interventions
- Aseptic Connections/Sterile Connectors
- Closed Systems
- Single-Use-Systems
- Biosafety
- Bio-Waste Treatment
- Lyophilization
- Blow-Fill-Seal/Form-Fill-Seal
- Application of EU GMP Annex 1 Requirement on New Modalities e.g. ATMPs
- Quality on the Shop Floor/Quality Oversight

9. PARTNERING AND COOPERATION IN ASEPTIC MANUFACTURING

- Relationship CDMO and Contract Giver
- Quality Systems Including Quality Agreements
- Project Management in Outsourcing
- Sourcing/Selection of CDMOs
- Increasing Expectations to CDMOs Regarding Quality and Service
- Technology Transfer (Manufacturing Process/Analytical Testing)
- Health, Safety and Environment
- From Product to Solution
- Expectations for Suppliers not Working Under GMP Regulation
- Defining Responsibilities to Comply with the Regulation
- Quality Oversight of CDMOs
- Influence of EU GMP Annex 1 on Sterile Medicinal Product Supply Chain

10. SUSTAINABILITY

- Profitable Economy Based on Degrowth
- Sustainability Versus Quality Assurance
- Eco-Design Guidelines for Machinery and Cleanrooms
- Eco-Balancing of Products and Processes
- Lifecycle Assessment Calculations
- Disposal Practices – Today and Tomorrow
- Packaging Designs and Material Selection
- Water, Waste, and Energy Reduction Programs (Equipment and Infrastructure)
- Reduction of Waste Water
- Equipment and Process Design for Material Waste Separation/Sorting
- Cleaning As Pathway for Re-Usage of Material
- 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
- EU Proposal for Packaging and Packaging Waste Regulation

SUBMISSION PROCESS

DEADLINE: 03 NOVEMBER 2023

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 are required to pay the conference registration fee.

Abstracts not selected for a podium presentation may be invited to join as a scientific poster contribution. On-site poster presenters are required to pay the conference registration fee and an additional printing fee will apply.

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 (MAX 300 WORDS)

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

bit.ly/3P1GdPj

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: 29 MARCH 2024

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:
120 dpi (low) - 150 dpi (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.**

JOIN OUR GUIDED POSTER WALK IN OUR EXHIBITION HALL AND GAIN MORE VISIBILITY

YOU WILL HAVE THE CHANCE TO ENGAGE WITH OUR POSTER AUDIENCE!

PDA EUROPE

CONFERENCES AND EVENTS

FOR FURTHER INFORMATION
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2024

11.Aug 2023

09-10 APR 2024	2024 PDA Visual Inspection Forum	Munich, Germany
23-24 APR 2024	2024 PDA Parenteral Packaging Conference	TBA
15-16 MAY 2024	2024 PDA Good Aseptic Manufacturing Conference	Stuttgart, Germany
04-05 JUN 2024	2024 PDA Good Digitalization in Pharma Conference	TBA
04-05 JUN 2024	2024 PDA Medical Devices and Connected Health Conference	TBA
06 JUN 2024	2024 PDA Artificial Intelligence in Pharma Workshop	TBA
06 JUN 2024	2024 PDA The Future of Drug Delivery Workshop	TBA
24-25 JUN 2024	2024 PDA Advanced Therapy Medicinal Products Conference	Amsterdam, The Netherlands
26-27 JUN 2024	2024 PDA Virus Conference	Amsterdam, The Netherlands
28 JUN 2024	2024 PDA Next-Generation Sequencing Workshop	Amsterdam, The Netherlands
24-25 SEP 2024	2024 PDA BioManufacturing Conference	Gothenburg, Sweden
26 SEP 2024	2024 PDA Sustainability in Pharma Workshop	Gothenburg, Sweden