2024 PDA

BIOMANUFACTURING CONFERENCE

pda.org/EU/2024BioMan

24-25 SEPTEMBER 2024
GOTHENBURG, SWEDEN
TRAINING: 23 - 24 SEPTEMBER 2024
EXHIBITION: 24 - 25 SEPTEMBER 2024
WORKSHOP: 26 SEPTEMBER 2024
TRAININGS: 26 - 27 SEPTEMBER 2024

CALL FOR ABSTRACTS

ABSTRACT SUBMISSION DEADLINE:
05 APRIL 2024

CONNECTING PEOPLE SCIENCE AND REGULATION®

WELCOME FROM THE CO-CHAIRS

Dear Colleague,

We would like to invite you to submit a paper or poster abstract for a presentation at the **2024 PDA BioManufacturing Conference** to take place on **24 - 25 September** in **Gothenburg, Sweden.**

Abstracts must be non-commercial in nature, describing new and innovative developments or work that significantly contributes to the body of knowledge relating to biomanufacturing 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

Sabine Hauck,
Consultant

Elisabeth Vachette,
Sartorius

CALL FOR ABSTRACTS

TOPICS AREAS OF INTEREST WILL INCLUDE BUT

1. ASEPTIC MANUFACTURING

- Single-Use Systems
- Aseptic Processing and Aseptic Process Validation
- Container Closure Integrity Testing
- Cleaning and Disinfection
- Contamination Control Strategy
- Environmental Monitoring
- Biosafety and High-Potent Ingredients
- Manufacturing Efficiency and Reliability
- Innovation in Fill and Finish
- Developments in Isolator Technology
- Aseptic Process Equipment
- Process Automation
- Implementation of EU GMP Annex 1: 2022 in Practice

2. SUPPLY CHAIN LOGISTICS AND FACILITIES

- Shortages of Consumables, Critical Raw Materials, Reagents, Sterilization Methods, etc.
- Validation Strategies
- Aging Facilities and Retrofit Strategies
- Strategies for Substitutions
- Multi-Sourcing Strategies
- Increasing Manufacturing and Distribution Capacity
- Post-Approval Changes in a Global Perspective
- CDMO Selection and Management
- Technology Transfer
- Capacity Planning
- Increasing Capabilities Through Partnerships

3. DEVELOPMENT AND LIFECYCLE STRATEGIES

- Preparedness for Future Health Emergencies
- Quality by Design and Advanced Control Strategies
- Use of Prior Knowledge for Manufacturing and Quality Control, Platform Approaches
- Accelerated Development
- Continuous Manufacturing, Process Intensification and Continuous Process Verification
- Comparability Strategies
- Technology Transfer
- ICH Trends - New Guidelines and Implementation (e.g., Q6B, Q5A, Q12, Q13, Q2(R2) / Q14)

4. PRODUCT APPROACHES

- Bio Betters and Biosimilars
- Precision Vaccinology, Prophylactic Vaccines, Specifications for Vaccines
- High-Concentration Biopharmaceuticals for Administration
- Antibodies and Related Products
- Live Biotherapeutics
- Antibiotics
- Enzymes and Enzyme Replacement Therapy
- Orphan Drugs
- Antibody-Drug Conjugates
- mRNA Platform Products, Inactivated Viral mRNA Vaccines
- Viral Vectors
- Nano Capsules
- Oligonucleotides
- Highly Potent/Toxic Substances
- Advanced Therapy Medicinal Products
- CRISPR-CAS9

5. UPSTREAM AND DOWNSTREAM PROCESSING

- Scale-Up/Scale-Down Models
- Cell Banking incl. Cryopreservation and Freeze-Drying
- Cell Culture
- New and Modified Culture Media
- High Yield Processes
- Novel Production Formats
- Virus Clearance
- Concentration and Purification Technology
- Freezing – Thawing Technologies for Large Volumes

CASE STUDIES AND CURRENT CHALLENGES ARE OF SPECIAL INTEREST.

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Sabine Hauck, *Consultant*
Elisabeth Vachette, *Sartorius*
Andrea Arsiccio, *Coriolis*
Adithya Balasubramanian, *ten23 health*
Bianca Bohrer, *PSM*
Cristiana Campa, *GSK*
Michael De Felippis, *Eli Lilly*
Sebastian Groel, *Boehringer Ingelheim*
Virginie Le Coent, *BioMerieux*
Julian Lenger, *Bayer*
Yves Mayeresse, *GSK*
Mic McGoldrick, *Merck Sharp & Dohme*
Maria Papathanasiou, *Imperial College London*
Josh Eaton, *PDA*
Falk Klar, *PDA Europe*
Sabine Hartmann, *Manager Programs & Events, PDA Europe*

ARE NOT LIMITED TO THE FOLLOWING

6. FORMULATION AND FILLING

- Formulation Technology
- Visual Inspection
- (Sub)-Visible Particles Characterization
- Process Control
- Serialization and Traceability
- New Developments for Filling Lines
- RABS/Isolator Technology
- Material Transfer from Filling to Lyophilization in Aseptic Environment
- In-Use Administration Studies and CSTD (Closed System Transfer Devices)

7. NEW TECHNOLOGIES AND INNOVATIONS

- Industry 4.0
- Innovations in Equipment
- Robotics and Automation
- Artificial Intelligence and Machine Learning
- Data Management and Data Analytics
- Modelling and Simulations, Process and Stability Modelling
- Predictive Modelling
- Augmented and Virtual Reality
- Digital Twins
- Modular Facilities and Multi-Purpose Facilities
- 3D Printing
- Real-Time Process Control/Feedback
- Genome Editing
- Simulations Tools (Computational Fluid Dynamics, etc.)

8. QUALITY CONTROL

- Analytical Development, Validation, and Lifecycle
- High-Throughput Testing
- Sterility Testing
- Contamination Testing (e.g., Endotoxin, RNAse, Particulate, Adventitious Agents, etc.)
- Extractables and Leachables
- Rapid Micro Methods
- Biological Assays
- In Vivo vs. In Vitro Strategies (incl. Organ-On-a-Chip, 3R Initiative, Horseshoe Crab Replacement, etc.)
- National Control Laboratories Testing
- Acceleration of Product Release and Access
- Process Analytical Technology
- Impact of ICH Q14

9. SUSTAINABILITY

- Reduction of Energy and Resource Consumption
- Environmental Protection, Controls, Standards
- Optimized Cycle Times
- Greenhouse Gases Regulation
- Alternative Natural Refrigerants
- Per- and Polyfluoroalkyl Substances (PFAS) Ban
- Application of AI for Sustainability
- Waste Management, Recycling, and Circular Economy
- Net Zero Initiative
- Development of Low Global Warming Products and Actions
- Suppliers and Manufacturers Collaboration
- Balance of Social, Economic and Ecological Responsibilities
- Life-Cycle Assessment (LCA) Methods & Use Cases

10. MANUFACTURING-RELATED REGULATORY ASPECTS

- Regulatory Perspective on Innovations
- Pharmacopoeias Considerations and Convergency
- Global Convergence of Regulatory Guidelines, Global Harmonization and Reliance
- Quality Risk Management
- Data Integrity in the Digital World
- Emerging Markets
- Inspection Trends
- Prevention of Drug Shortages
- Data Integrity Regulations on Supply Chain
- EU Regulations on Drug Shortages

11. FREEZE – DRYING

- Primary Containers (Syringes, Polymer Material and Nested Rack Systems)
- Advanced Equipment/ Inovated Techonology
- Loading/Unloading Systems
- Controlled Nucleation Techniques
- Alternative Refrigerants in the Light of EU Legislation to Control F-Gases
- Continuous Lyophilization and Alternative Technologies (e.g., Spray Freeze-Drying, Foam Drying, Spin/Shell Freezing)
- Process Development and Optimization
- Solid State Analytical Techniques
- New Modalities Including Viruses, Virus-Like Particles and Lipid Nanoparticles
- PAT Tools and Process Monitoring
- Impact of EU GMP Annex 1:2022 on Lyophilization
- Containment Strategies for High-Potency Active Pharmaceutical Ingredients (HPAPI)
- Emerging Excipients

SUBMISSION PROCESS

DEADLINE: 05 APRIL 2024

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)

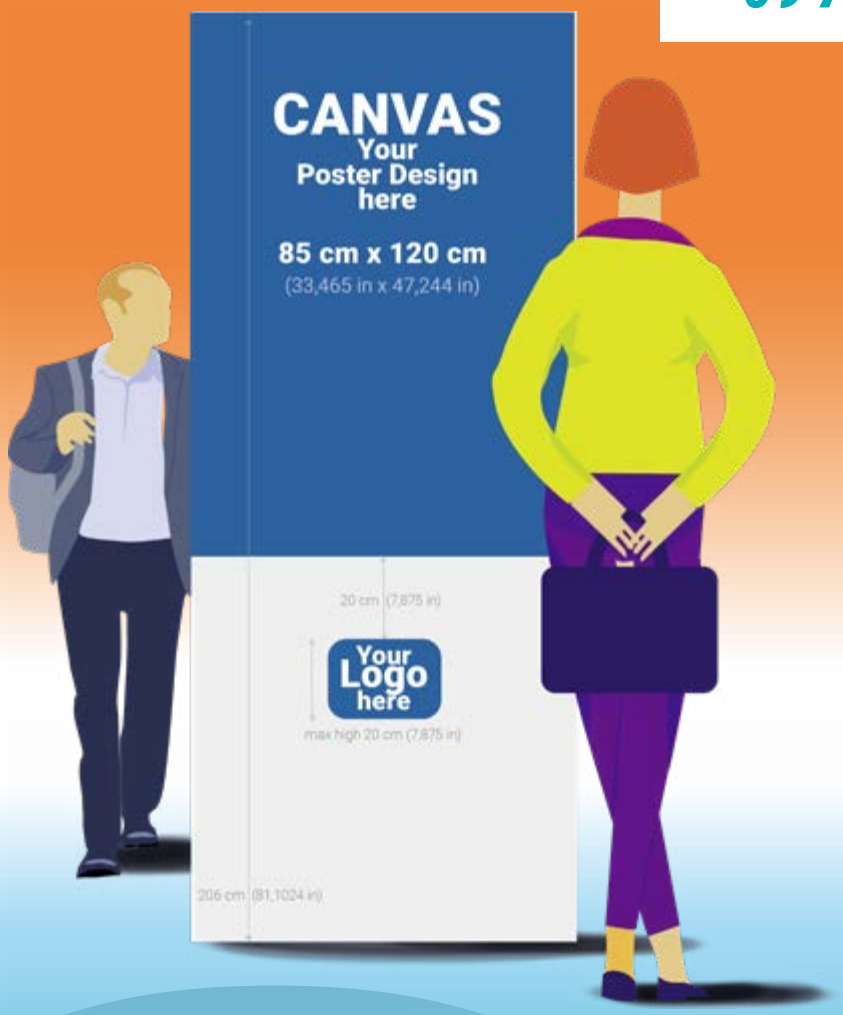
Please click or scan the QR Code to submit your abstract.

https://bit.ly/488rxoQ

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: 09 AUGUST 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:
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.

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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www.pda.org

2024

13. February 2024

09-10 APR 2024	2024 PDA Visual Inspection Forum	Munich, Germany
23-24 APR 2024	2024 PDA Parenteral Packaging Conference	Copenhagen, Denmark
15-16 MAY 2024	2024 PDA Good Aseptic Manufacturing Conference	Stuttgart, Germany
04-05 JUN 2024	2024 PDA Good Digitalization in Pharma Conference	Antwerp, Belgium
04-05 JUN 2024	2024 PDA Medical Devices and Connected Health Conference	Antwerp, Belgium
06 JUN 2024	2024 PDA Artificial Intelligence in Pharma Workshop	Antwerp, Belgium
06 JUN 2024	2024 PDA The Future of Drug Delivery Workshop	Antwerp, Belgium
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
04-06 SEP 2024	2024 PDA Manufacturing Meets Legislation Workshop	Berlin, Germany
24-25 SEP 2024	2024 PDA BioManufacturing Conference	Gothenburg, Sweden
26 SEP 2024	2024 PDA Sustainability in Pharma Workshop	Gothenburg, Sweden
05-06 NOV 2024	2024 PDA Annex 1 Workshop	Dublin, Ireland