**2022 PDA** 

# BIOMANUFACTURING CONFERENCE



pda.org/EU/BioMan2022

20-21 SEPTEMBER 2022 AMSTERDAM, THE NETHERLANDS

EXHIBITION: 20-21 SEPTEMBER 2022 TRAINING: 22-23 SEPTEMBER 2022



#### WELCOME FROM THE CHAIRS

Dear Colleague,

We would like to warmly invite you to submit a paper or poster abstract for presentation at the **2022 PDA BioManufacturing Conference** to be held on **20-21 September 2022** as a **Face-to-Face Event.** An online platform will offer possibilities for remote presentation and participation in support of the face-to-face event!

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

Sincerely, The Chairs



Cristiana Campa, GSK Vaccines



**Raf De Dier,**Janssen

## CALL FOR ABSTRACTS

### TOPICS AREAS OF INTEREST WILL INCLUDE



#### 1. ASEPTIC MANUFACTURING

- · Single-Use Systems
- Aseptic Processing and Aseptic Process Validation
- Process Development and Process Control
- Container Closure Integrity Testing
- · Cleaning and Disinfection
- · Contamination Control
- · Environmental Monitoring
- Biosafety and High-Potent Ingredients
- Continuous Processing
- Developments in Isolator Technology



## 2.MANAGING CHANGES IN SUPPLY CHAIN LOGISTICS

- Shortages of Consumables, Critical Raw Materials and Reagents
- Validation Strategies
- Aging Facilities
- Strategies for Substitutions
- · Multi-Sourcing Strategies
- Increasing Manufacturing and Distribution Capacity
- Post-Approval Changes in a Global Perspective
- CMO Selection and Management
- Technology Transfer
- Increasing Capabilities by Partnerships



# 3. DEVELOPMENT AND LIFECYCLE STRATEGIES

- Learnings from COVID-19
   Pandemics and Preparedness for Future Health Emergencies
- Quality by Design and Advanced Control Strategies
- Prior Knowledge and Platform Approaches
- Accelerated Development
- Continuous Process Verification
- · Comparability Strategies
- Process Analytical Technology
- · Technology Transfer
- ICH Q5A, Q12, Q13, Q2(R2) / Q14
- ICH Guidelines Future Revisions

   Stability and Specifications
   Strategies



#### 4. PRODUCT APPROACHES

- Bio Betters and Biosimilars
- Novel Vaccines
- · Antibodies and Related Products
- Live Biotherapeutics
- Antibiotics
- Enzymes and Enzyme Replacement Therapy
- Orphan Drugs
- Immunotherapy
- · Antibody-Drug Conjugates
- mRNA Platform Products
- · Nano Capsules
- Oligonucleotides
- · Highly Potent / Toxic Substances

#### SCIENTIFIC PROGRAM PLANNING COMMITTEE

Marta Antunes, MSD

Thomas Beutler, GEA Lyophil GmbH

Michael De Felippis, Eli Lilly and Company

Thierry Gastineau, Sanofi-Pasteur SA

Sabine Hauck, Leukocare AG

Susanne Joerg, ten23 health AG

Julian Lenger, Bayer AG

Joerg Luemkemann, La Roche AG

Yves Mayeresse, GSK Vaccines

Arnaud Paris, BioMerieux

Elisabeth Vachette, Sartorius Stedim Biotech SA

Diane Wilkinson, AstraZeneca

Josh Eaton, PDA

Falk Klar, PDA

Sabine Hartmann, Manager Programs & Events, PDA





**HILTON AMSTERDAM** 

Apollolaan 138, 1077 BG, Amsterdam, The Netherlands https://bit.ly/3uYaKoW

#### BUT ARE NOT LIMITED TO THE FOLLOWING



#### 5. UPSTREAM & DOWN-STREAM PROCESSING

- Scale-Up / Scale-Down Models
- · Cell Banking
- · Cell Culture
- · New and Modified Culture Media
- High Yield Processes
- · Novel Production Formats
- · Virus Clearance
- Concentration and Purification Technology



#### 9. SUSTAINABILITY

- Ecological Footprint
- Reduction of Energy and Resource Consumption
- Green Technology
- Environmental Protection, Controls, Standards
- Optimized Cycle Times
- Fluorinated Greenhouse Gases Regulation
- Alternate / Natural Refrigerants
- Circular Economy
- Waste Management and Recycling



#### 6. FORMULATION AND **FILL & FINISH**

- · Primary Containers
- · Visual Inspection
- · Freeze-Drying Equipment, Process and Development
- Alternate Technologies (Blow Fill Seal / Continuous Spray Drying, Shell / Spin Freezing)
- Process Control
- Extractables and Leachables
- Serialization
- New Developments for Filling Lines
- Formulation Science and Thermostability



#### 7. NEW TECHNOLOGIES **AND INNOVATIONS**

- Industry 4.0
- Innovations in Equipment
- Robotics
- Artificial Intelligence and Machine Learning
- Data Analytics
- · Modelling and Simulations
- Augmented and Virtual Reality
- Digital Twins
- Modular Facilities and Multi-Purpose Facilities
- Real-Time Process Control / Feedback



#### 8. TESTING

- Analytical Development, Validation and Lifecycle and Impact of ICH Q14
- · High-Throughput Testing
- · Sterility Testing
- **Endotoxin Testing**
- Rapid Micro Methods
- · Biological Assays
- In Vivo vs. In Vitro Strategies
- National Control Laboratories Testing
- Acceleration of Product Release and Access



#### 10. MANUFACTURING RELATED REGULATORY ASPECTS

- Regulatory Perspective on Innovations
- · Revision EU GMP Annex 1 in Practice
- · Pharmacopoeias Considerations and Convergency
- · Quality Risk Management
- Data Integrity in the Digital World
- · Emerging Markets
- · Inspection Trends
- Post-Emergency Scenarios -The "New Normal"
- Global Harmonization
- Pandemic Preparedness

# **DEADLINE:** 29 APR 2022

# 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

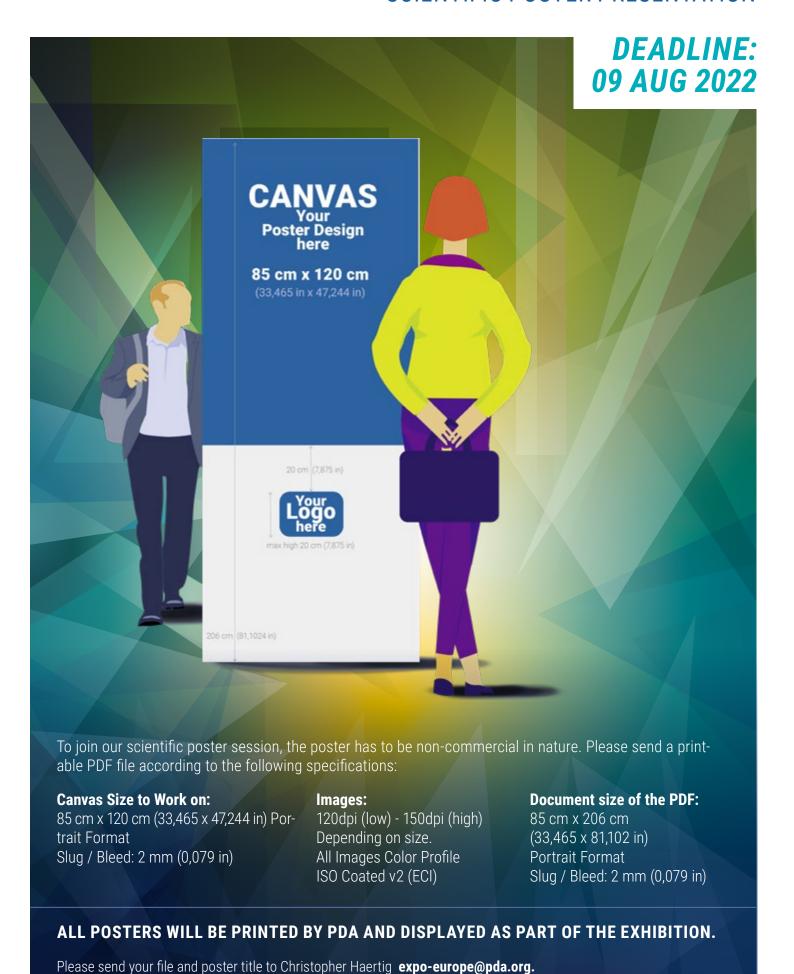
Please click or scan the QR Code to submit your abstract.



https://bit.ly/3JFYoWB

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.** 



## **PDA EUROPE**

# UPCOMING CONFERENCES AND EVENTS



FOR FURTHER INFORMATION FOLLOW US ONLINE

www.pda.org

2022	22. Feb 2022	
26-27 APR 2022	2022 PDA Visual Inspection Forum	Berlin, Germany
16-17 MAY 2022	2022 PDA Medical Devices and Connected Health Conference	Dublin, Ireland
16-17 MAY 2022	2022 PDA Robotics and Automation Conference	Dublin, Ireland
18-19 MAY 2022	2022 PDA Annex 1 Workshop	Dublin, Ireland
02-03 JUN 2022	2022 PDA Parenteral Packaging Conference	Basel, Switzerland
20-21 JUN 2022	2022 PDA Virus Conference	Brussels, Belgium
22-23 JUN 2022	2022 PDA Advanced Therapy Medicinal Products Conference	Brussels, Belgium
20-21 SEP 2022	2022 PDA BioManufacturing Conference	Amsterdam, The Netherlands
22-23 SEP 2022	2022 PDA Annex 1 Workshop	Amsterdam, The Netherlands
05-06 OCT 2022	2022 PDA Quality and Regulations Conference	Amsterdam, The Netherlands