

2021 PDA BIOMANUFACTURING CONFERENCE





EUROPE

EXHIBITION: 14-15 SEPTEMBER TRAINING: 16-17 SEPTEMBER

CONNECTING PEOPLE SCIENCE AND REGULATION®

ABSTRACT SUBMISSION DEADLINE: 9 APRIL 2021

Dear Colleague,

We warmly invite you to submit an abstract for a podium or poster presentation for the **2021 PDA BioManufacturing Conference** to be held on **14-15 September 2021** as a **Hybrid Event** offering the option of either in person or virtual participation. PDA Europe's online platform will ensure a full conference experience regardless of how participants choose to connect.

This year's conference will focus on **Biomanufacturing in the New Era.** While the COVID- 19 emergency has unquestionably defined the start of a new phase for biopharmaceuticals and related aspects in manufacturing, quality control and regulation, issues such as acceleration, product supply, manufacturing capacity, innovative technologies, high-throughput manufacturing and rapid analytical testing, product accessibility are not necessarily new.

The pandemic simply put into greater focus the relevancy and urgency of these issues and the need for industry to make necessary changes to speed delivery of pharmaceutical innovation. In addition, the crisis has evidenced the need for flexible regulatory frameworks and concurrence across Health Authorities to support rapid access of vaccines and biotherapeutics as well as sustainable lifecycle management. The 2021 BioManufacturing Conference will emphasize many of these topics ensuring a balanced perspective from Academia, Industry representatives and Regulators.

Sincerely, The Co-Chairs



Cristiana Campa, *GSK Vaccines*



Michael De Felippis, Eli Lilly & Company

Call for Abstracts Topics areas of interest will include but are no



1. ASEPTIC MANUFACTURING

- Single-Use Systems
- · Facility Set-Up
- · Environmental Monitoring
- Biosafety and High Potent Ingredients
- · Cleaning and Disinfection
- · Continuous Processing
- Clean Room Design and the Human Factor
- 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
- Increasing Manufacturing and Distribution Capacity
- Post-Approval Changes in a Global Perspective
- Increasing Capabilities by Partnerships



3. DEVELOPMENT AND LIFECYCLE STRATEGIES

- Learnings from COVID-19 Pandemics and Impact on Future CMC Strategies
- Advanced Control Strategies / Quality by Design
- Prior Knowledge and Platform Approaches
- Accelerated Development
- · Comparability Strategies
- Introduction of Product Innovations
- Tech Transfer
- Specification Settings
- ICH Q5A, Q12, Q13, Q2/Q14



4. PRODUCT APPROACHES

- · Biobetters and Biosimilars
- · Novel Vaccines
- Antibodies and Related Products
- Enzymes & Enzyme Replacement Therapy
- Orphan Drugs
- Immunotherapy
- · New Modalities
- Developments and Expectations



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

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Cristiana Campa, GSK Vaccines, Chair

Michael De Felippis, Eli Lilly & Company, Chair

Glen Bolten, Amgen

Lucia Ceresa, Charles River

Richard Denk, SKAN

Thierry Gastineau, Sanofi Pasteur

Walid El-Azab, STERIS

Susanne Joerg, LONZA

Arnaud Paris, BioMérieux

Jonny Parsons, Amgen

Sebastian Teitz, Asahi Kasei

Elisabeth Vachette, Sartorius Stedim

Mark van Ooij, Janssen Vaccines

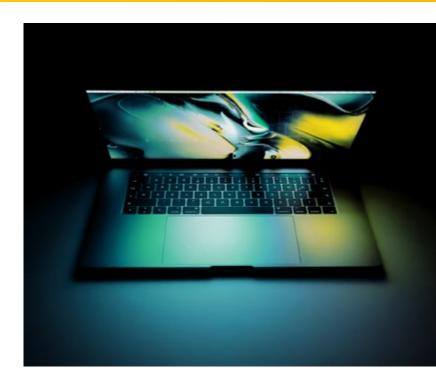
Florence Wauters, MSD

Diane Wilkinson, AstraZeneca

Josh Eaton, PDA

Falk Klar. PDA Europe

Teresa Schubach, Manager Programs & Events, PDA Europe



t limited to the following



6. FORMULATION AND FILL & FINISH

- · Primary Containers
- Visual Inspection
- Lyophilization
- Extractables and Leachables
- · Container/Closure Integrity
- Blow-Fill Seal
- · Serialization
- New Developments for Filling Lines
- Microbiological Control Strategies
- · Formulation Science



7. NEW TECHNOLOGIES AND INNOVATIONS

- · Industry 4.0
- Robotics
- Artificial Intelligence and Machine Learning
- · Automation and Digitalization
- Data Analytics
- · Modelling Approaches
- · Augmented and Virtual Reality



8. TESTING

- Analytical Development, Validation and Life-Cycle
- · High-Throughput Testing
- · Sterility Testing
- Endotoxin Testing
- · Rapid Micro Methods
- · Biological Assays
- · In Vivo vs. In Vitro Strategies
- National Control Laboratories Testing
- Acceleration of Vaccine Release and Access
- Learnings for Post-Emergency Scenarios



9. SUSTAINABILITY

- Sustainable Manufacturing
- Ecological Footprint
- Carbon Footprint
- Reduction of Energy Consumption
- Green Technology
- · Circular Economy
- · Ecological Footprint
- Eco-Efficiency
- Environmental Protection, Controls, Standards
- · Resource Consumption
- Waste Management and Recycling
- · Protecting the Eco-System



10. MANUFACTURING RELATED REGULATORY DISCUSSIONS

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

PDA Submission Process

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

All submitted abstracts will be reviewed by the Scientific Program Planning Committee for acceptance. PDA Europe will provide a complimentary registration per virtual or onsite podium presentation. Additional on-site presenters and 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.

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



Deadlines

Abstracts for Podium Presentation: 9 April 2021 Printfile for Poster Session: 30 July 2021

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 on-site and virtually. 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 Scientific Poster Presentation

Exhibit Your Work



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)

VIRTUAL EVENT:

Document Size of the PDF: Each Poster DIN A4

Poster Abstract:

Maximal 1500 characters

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 EVENTS



2021		
20-21 APR 2021	2021 PDA Robotics and Automation Conference	Online
27-28 APR 2021	2021 PDA Parenteral Packaging Conference	Online
18-19 MAY 2021	2021 PDA Quality and Regulations Conference	Online
08-09 JUN 2021	2021 PDA Annex 1 Conference	Dublin, Ireland and Online
21-22 JUN 2021	2021 PDA Virus Conference	Brussels, Belgium and Online
23-24 JUN 2021	2021 PDA Advanced Therapy Medicinal Products Conference	Brussels, Belgium and Online
14 -15 SEP 2021	2021 PDA BioManufacturing Conference	TBC, Europe and Online
16-17 SEP 2021	2021 PDA Pharmaceutical Lyophilization Conference	TBC, Europe and Online
05-06 OCT 2021	2021 PDA Universe of Pre-Filled Syringes and Injection Devices Conference	Gothenburg, Sweden and Online
26-27 OCT 2021	2021 PDA Aseptic Animal Health Conference	Online



GENERAL INFORMATION

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