

2021 PDA PHARMACEUTICAL LYOPHILIZATION CONFERENCE

CALL FOR ABSTRACTS



16-17 SEPTEMBER 2021
BERLIN, GERMANY
EXHIBITION: 16-17 SEPTEMBER

WELCOME FROM THE CHAIRS

Dear Colleague,

We would like to invite you to submit a paper or poster abstract for presentation at the **2021 PDA Pharmaceutical Lyophilization Conference, 16-17 September in Berlin, Germany, a Hybrid Event**. An online platform will offer possibilities for remote presentation and participation in support of a face-2-face event.

Sincerely,

The Chairs



Anthony Cannon,
MSD



Raf De Dier, PhD,
Janssen J&J

CALL FOR ABSTRACTS TOPICS AREAS OF INTEREST WILL INCLUDE



1. REGULATORY UPDATES

- Implications of Annex 1 Revision
- Inspection Trends
- Aseptic Process Validation
- Container Closure Integrity Testing
- Point of Fill-Filtration and PUPSIT for Lyo-Product



2. MANUFACTURING TRENDS

- Alternate Technologies
 - Continuous/Spray Drying, Shell/Spin Freezing
- Low Temperature Drying
- Fogging
- Controlled Nucleation
- Process Development for Generics, Proteins, Biologics, Vaccines
- Spray Drying and Spray Freeze-Drying



3. LYO BY PRODUCT TYPE, HANDLING, STABILITY CONSIDERATIONS

- Active Pharmaceutical Ingredients (APIs)
- Advanced Therapy Medicinal Products (ATMPs)
- Antibody-Drug Conjugates (ADCs)
- Vaccines
- mAbs
- Biosimilars
- Live Biotherapeutics
- Nanocapsules
- Oligonucleotides
- Bulk Intermediates
- Small Volumes
- Highly Potent/Toxic Substances



4. GREEN MANUFACTURING

- Ecological Footprint
- Carbon Dioxide Footprint
- Reduction of Energy Consumption
- Optimized Cycle Times
- Fluorinated Greenhouse Gases (F-Gases) Regulation
- Environmental Protection
- Alternate Refrigerants
- Recycling Potential of Solvent-Based Drying

SCIENTIFIC PROGRAM PLANNING COMMITTEE

- Anthony Cannon**, MSD, Chair
- Raf De Dier**, Janssen J&J, Chair
- Thomas Beutler**, GEA
- Thomas Frank**, Refolution
- Julian Gitter**, Bayer
- Sebastian Groel**, LMU Munich
- Maik Guttzeit**, Bayer
- Sabine Hauck**, Leukocare
- Petra Knerr**, Martin Christ
- Jörg Lümke**, F. Hoffmann – La Roche
- Yves Mayeresse**, GSK
- Sascha Pfeiffer**, Pharmbiocon
- Kevin Smyth**, IPS
- Josh Eaton**, PDA
- Falk Klar**, PDA Europe
- Sylvia Becker**, Senior Manager Programs & Events, PDA Europe



BUT ARE NOT LIMITED TO THE FOLLOWING



5. EQUIPMENT

- Robotics and Automation
- Sensors
- Wireless Probes
- Camera Systems
- Visual Inspection (automated/semi-automated/manual)
- Cleaning in Place
- Sterilization in Place
- Refrigeration System
- Loading/Unloading Systems
- Silicon Oil Contamination



6. PRIMARY CONTAINERS

- Glass Vials
- Stoppers
- Capping
- Plastic Polymer Containers
- Headspace Analysis
- Container Closure Integrity
- Loading/Unloading of Nested Vials
- Vial Breakage
- Dual Chamber Containers
- Extractables and Leachables



7. PROCESS CONTROL

- Pressure Monitoring
- Temperature Measurement
- Heat Flux Measurement
- Headspace Moisture Measurement
- Impedance Spectroscopy
- Mass Spectrometry
- Thermal Mapping
- Digitalization
- Leak Rates
- Cake Appearance
- Equipment Characterization
- Track and Trace for Freeze-Dried Products



8. PROCESS ENVIRONMENT

- Decontamination
- Challenges with Hydrogen Peroxide
- Transportation Systems
- Closed Systems
- Vial Washing
- Operator Safety



9. PROCESS DEVELOPMENT

- Process Optimization, Robustness
- Smart Lyophilization
- Freeze Drying Microscope
- Modelling
- Quality By Design
- Design of Experiment
- Formulation Design



10. QUALITY ASPECTS

- Process Analytical Technology
- Control Strategy
- Continuous Process Verification
- Process & Product Validation
- Critical Quality Attributes
- Matrixing Strategies
- Bracketing Approach
- Acceptable Reject Rates
- Stability Indicating Technologies
- Homogeneity Validation



11. CONTRACT MANUFACTURING

- CMO Selection
- CMO Management
- Process Development
- Technology Transfer
- Aseptic Processing
- Upscaling

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 on-site 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.



<https://bit.ly/3f0N9PP>

Deadlines

Abstracts for Podium Presentation: **4 June 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 or via telephone +49 30 436 5508 23.

PDA Scientific Poster Presentation

Exhibit Your Work

Deadline:
30 July 2021



FACE TO FACE CONFERENCE:

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)

VIRTUAL EVENTS ONLY:

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

18-19 MAY 2021	2021 PDA Quality and Regulations Conference	Online
08-09 JUN 2021	2021 PDA Annex 1 Conference	Online
21-22 JUN 2021	2021 PDA Virus Conference	Online
23-24 JUN 2021	2021 PDA Advanced Therapy Medicinal Products Conference	Online
14 -15 SEP 2021	2021 PDA BioManufacturing Conference	Berlin, Germany and Online
16-17 SEP 2021	2021 PDA Pharmaceutical Lyophilization Conference	Berlin, Germany 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