

2021 PDA ANNEX 1 CONFERENCE

CALL FOR ABSTRACTS



8-9 JUNE 2021
DUBLIN, IRELAND
EXHIBITION: 8-9 JUNE
TRAINING: 10-11 JUNE

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 Annex 1 Conference** to be held on **8-9 June in Dublin/Ireland!** Abstracts must be non-commercial in nature, describing new developments or work that significantly contributes to the body of knowledge relating to the new revision of EU GMP Annex 1.

The conference will take place as a **Hybrid Event** with an online platform allowing for remote participation and presentation in support of the face-to-face meeting!

Sincerely,

The Chairs



Hal Baseman,
ValSource



Gabriele Gori,
GSK

Call for Abstracts

Topics areas of interest will include but are not



1. GUIDELINE DEVELOPMENT

- Purpose
- Scope and position in EU regulatory landscape
- Relationship to US FDA Guidance Sterile Drug Products Produced by Aseptic Processing
- History of revisions
- Commenting process
- Wording and definitions
- Expectation by regulators
- Expectation by industry

2. CONTAMINATION CONTROL STRATEGY

- Principle of holistic approach
- Quality risk management
- Principles of risk assessment
- Definition of control strategy objectives
- Development of contamination control strategy
- Practical implementation
- Monitoring strategies
- Pharmaceutical quality system

3. ASEPTIC PROCESS VALIDATION

- Design of validation studies
- Acceptance criteria
- Number of media fills
- Practical implementation

4. REQUIREMENTS ON FACILITIES AND UTILITIES

- Water and water systems
- Steam
- Compressed gases
- Sterile filtration of gases
- Cooling systems
- Disinfection procedures
- Impact on facility design

5. CLEAN ROOMS AND BARRIER TECHNOLOGIES

- Relationship to ISO 14644
- Relationship to EU GMP Annex 15 (Qualification)
- Differences between classification, qualification and monitoring
- Definition of clean room classes
- airlocks and pass-boxes
- Pressure differences
- Management and handling of material
- RABS
- Isolator

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Gabriele Gori, GSK - Chair

Hal Baseman, ValSource - Chair

Darren Beckett, Sterility Solutions

John Henchion, Cagents

Andrew Hopkins, Abbvie

Brid Lynch, J&J

Janie Miller, PDA

Falk Klar, PDA Europe

Sylvia Becker, PDA Europe Senior Manager Programs & Events

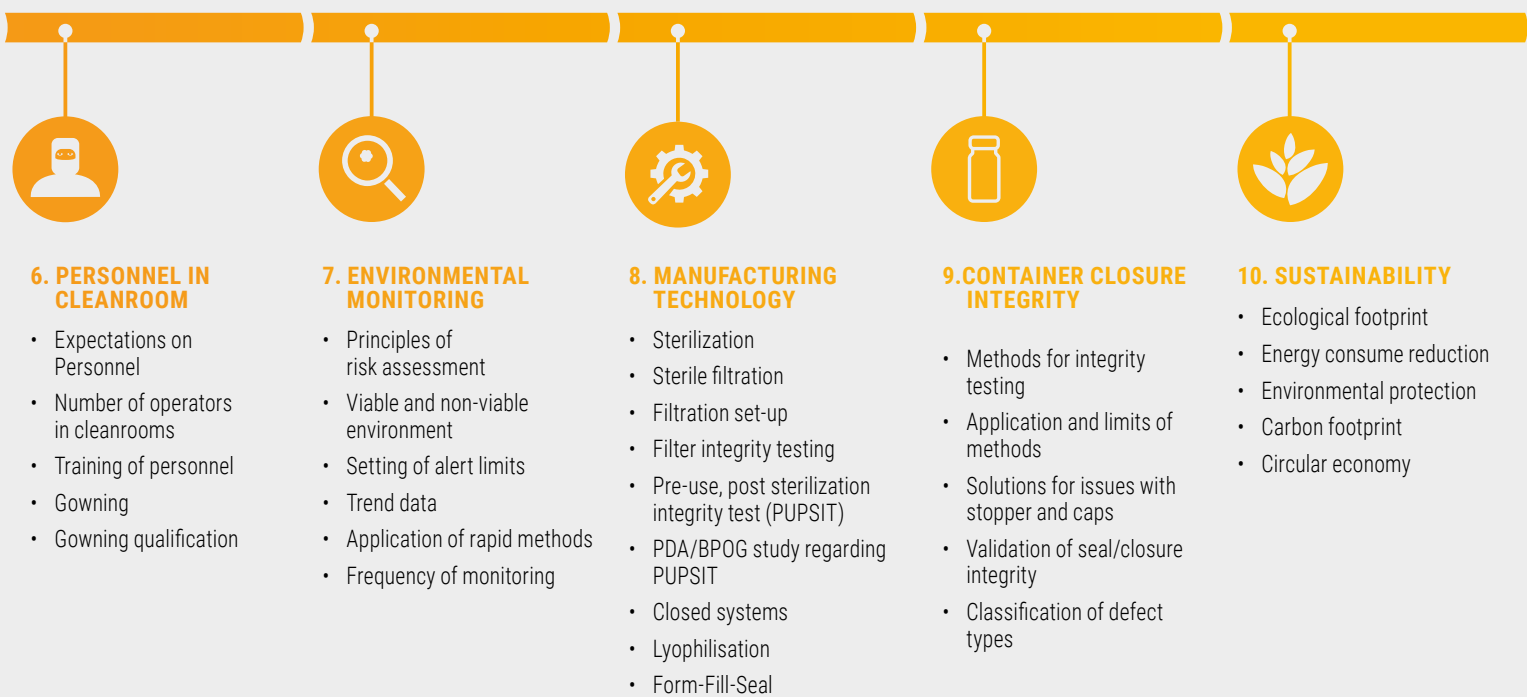


VENUE

Crowne Plaza Dublin Airport

Northwood Park, Santry Demesne,
Dublin, Ireland
bit.ly/34tMJVY

limited to the following



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/3ibrkZK>

Deadlines

Abstracts for Podium Presentation: **5 March 2021**

Printfile for Poster Session: **23 April 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

Deadline:
23 April 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:

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
26 APR 2021	2021 PDA Pre-Filled Syringes Workshop	Online
27-28 APR 2021	2021 PDA Parenteral Packaging Conference	
29 APR 2021	2021 PDA Packaging Science Workshop	
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