PDA Parenteral Drug Association

www.pda.org/EU/2021QR

2021 PDA QUALITY AND REGULATIONS CONFERENCE

A New Risk Landscape in an Evolving Quality & Regulatory Environment

CALL FOR ABSTRACTS

18-19 MAY 2021

LIVE | **INTERACTIVE** | ONLINE

CONNECTING PEOPLE SCIENCE AND REGULATION®

ABSTRACT SUBMISSION DEADLINE: 12 MARCH 2021

Dear Colleague,

We would like to invite you to submit an abstract for virtual podium or poster presentation at the **PDA Quality and Regulations Conference** to take place **online** on **18-19 May 2021.** Abstracts must be non-commercial in nature, describing new developments or work that significantly contributes to the body of knowledge relating to Quality and Regulations.

Sincerely,

The Chairs

Vinny Browning III, *Amgen*

Karin Baer, *Consultant*

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Vinny Browning III, *Amgen - Chair*

Karin Baer, *Consultant - Chair*

Graham Cook, *Pfizer*

Patrick Costello, *Abbvie*

Travis Frick, *GSK*

Peter Reichert, *Zelect*

Eva Urban, *CSL Behring*

Ruth Miller, *PDA*

Falk Klar, *PDA Europe*

Sylvia Becker, *PDA Europe, Senior Manager Programs & Events*

Call for Abstracts

Topics areas of interest will include but are not limited to the following

1. INTERNATIONAL REGULATORY FRAMEWORK

- Regulatory agencies' updates
- Global product registration
- Post-approval changes
- API import certification
- Sourcing of raw materials/ ingredients
- Transfer to/from United Kingdom after Brexit

2. INTERNATIONAL REGULATORY CONVERGENCE

- Mutual Recognition Agreement process
- International Council for Harmonization (ICH)
- Landscape and structure of ICH guidelines
- ICH Q- series

3. QUALITY SYSTEMS AND APPLICATIONS

- Pharmaceutical Quality System
- Quality Risk Management
- Quality by Design
- Real-time release
- Process analytical technology
- Risk analysis tools
- Deviation System
- Out of Specification Management
- Change Control system
- Complaint management
- Document control system
- Considerations for combination devices and the associated software

4. GXP AND GLOBAL PHARMACOPOEIAS

- Journey from research & development to supply chain - from GLP/GCP to GDP
- Ramping up GMP following the steps of drug development
- Interlinkage of GLP, GCP, GMP and GDP
- Updates on monographs
- Commenting process
- Pharmacopeial Discussion Group (PDG) and PDG process

5. INSPECTIONS

- Inspection trends
- Inspection process
- Remote inspections
- Remediation process
- Experiences with MRA US-EU

6. IMPLEMENTATION OF QUALITY IN MANUFACTURING/TESTING

- Microbiology/Rapid Micro Methods
- Environmental Monitoring
- Contamination Control Strategies
- Control strategies
- Quality lifecycle
- PUPSIT
- Drug shortages
- Qualification
- Validation
- Outsourcing
- Technology Transfer
- Role & responsibilities of the Qualified Person

7. DIGITAL APPLICATIONS IN QUALITY

- Internet of Things/Industry 4.0
- Automation
- Data analytics
- Big data
- Data integrity
- Data security
- Artificial intelligence
- Augmented reality
- Blockchain technology
- Digital Twins
- Machine Learning
- Factory of the future

8. SUSTAINABILITY

- Ecological footprint
- Energy consume reduction
- Environmental protection
- Carbon footprint

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 event registration per virtual podium presentation. Abstracts not selected for a virtual podium presentation may be invited to join as a scientific online poster contribution.

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

https://bit.ly/3n9dyZt

Deadlines
Abstracts for Virtual Podium Presentation: **12 March 2021**
PDF File for Poster Session: **2 April 2021**

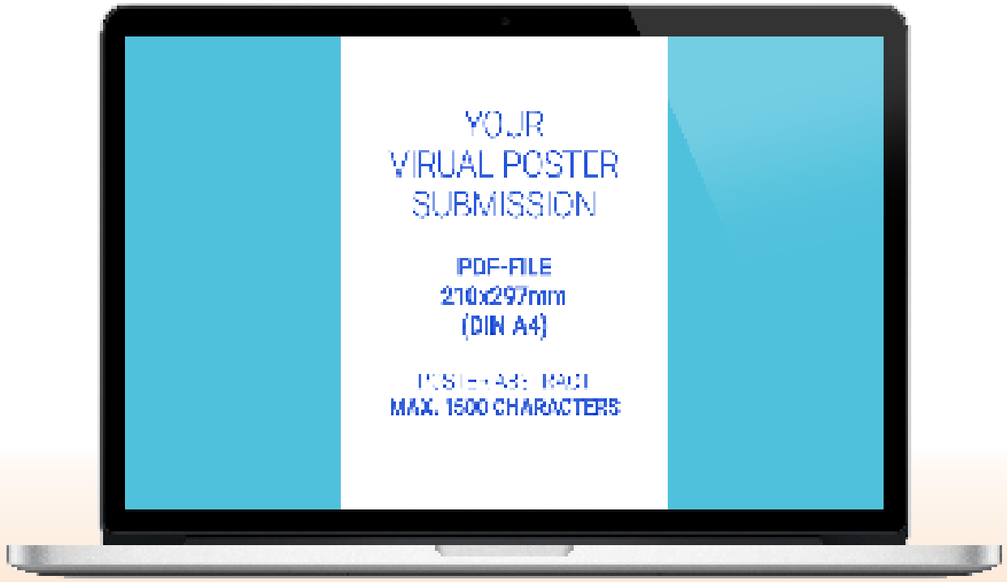
If you have any further questions, please do not hesitate to contact programs-europe@pda.org

To Exhibit:
PDA is seeking vendors who provide products / services in support of this conference.
To reserve your virtual booth, please contact, expo-europe@pda.org or via telephone +49 30 436 55 08 23.

PDA Scientific Poster Presentation

Exhibit Your Work Online

Deadline:
2 April 2021



To join our scientific poster session, the poster has to be non-commercial in nature. Please send a PDF file according to the following specifications:

VIRTUAL EVENTS:

Document Size of the PDF:
Each Poster DIN A4

Poster Abstract:
Maximal 1500 characters

All posters will be displayed as part of the virtual 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 27-28 APR 2021 29 APR 2021	2021 PDA Pre-Filled Syringes Workshop 2021 PDA Parenteral Packaging Conference 2021 PDA Packaging Science Workshop	Online
18-19 MAY 2021	2021 PDA Quality and Regulations Conference	Online
08-09 JUN 2021	2021 PDA Annex 1 Conference	Dublin, Ireland
21-22 JUN 2021	2021 PDA Virus Conference	Brussels, Belgium
23-24 JUN 2021	2021 PDA Advanced Therapy Medicinal Products Conference	Brussels, Belgium
14 -15 SEP 2021	2021 PDA BioManufacturing Conference	TBC, Europe
16-17 SEP 2021	2021 PDA Pharmaceutical Freeze Drying Technology Conference	TBC, Europe
05-06 OCT 2021	2021 PDA Universe of Pre-Filled Syringes and Injection Devices Conference	Gothenburg, Sweden
26-27 OCT 2021	2021 PDA Aseptic Animal Health Conference	Online

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