2022 PDA

QUALITY & REGULATIONS CONFERENCE

pda.org//EU/QualityR22

5-6 OCTOBER 2022
AMSTERDAM, THE NETHERLANDS
EXHIBITION: 5-6 OCTOBER

REGISTER BEFORE 7 AUGUST AND SAVE UP TO €200!

WELCOME FROM THE CHAIRS

Dear Colleagues,

"How industry and regulators will use data to drive continuous improvement of products and better patient outcomes." The recent pandemic has demonstrated the adaptability of humans during a global crisis. The use of novel technologies to manufacture vaccines, the regulatory approaches to see data review as an iterative process during the review of an application, as well as remote quality oversight of manufacturing sites have shown the flexibility of the pharmaceutical / medical device industry. As we move to the post-pandemic phase, we should not lose these approaches instead they should be fostered as the routine within our organizations. How we use data over the lifecycle of products will become a competitive advantage to any organization that fully embraces "Big Data".

While there have been many conferences on "Big Data", the distinguisher for this event is the use of big data from a regulator and industry perspective in the context of quality and regulatory compliance. How do we use data contained within our quality systems, manufacturing sites, labs, etc. to drive continued product and process knowledge? We will listen to Regulators from the FDA, EMA, etc. as to how they use data provided by clinical trial sponsors, marketing authorization holders, manufacturers, parallel importers/distributors, post-market complaint and pharmacovigilance data to develop quality oversight. Leading industry speakers will discuss initiatives implemented in case of study format the "how-to" use this data to drive product and process improvements.

Sincerely,
The Chairs

Vinny Browning III,
Amgen

Patrick Costello,
AbbVie

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Vinny Browning III, *Amgen, Chair*
Patrick Costello, *AbbVie, Chair*
Karin Baer, *NeuroDerm*
Daniel Davis, *GSK*
Travis Frick, *Adverum Biotechnologies*
Jette Johansen, *Novo Nordisk*
Peter Reichert, *Zelect Quality*
Eva Urban, *CSL Behring*
Anette Yan Marcussen, *Novo Nordisk*
Glenn Wright, *PDA*
Falk Klar, *PDA Europe*
Sabine Hartmann, *Manager Programs & Events, PDA Europe*

WELCOME TO QUALITY & REGULATIONS CONFERENCE

COVID-19 PERSONAL PRECAUTIONARY MEASURES

PDA is committed to deliver safe and secure in-person events. In conjunction with the venue and vendors supporting our event, PDA strictly adheres to all national, provincial and local government regulations.

Photo by Massimo Virgilio on Unsplash

CONFERENCE AGENDA

WEDNESDAY, 5 OCTOBER 2022		09:00 – 17:15
9:00	**Welcome and Introduction**	Falk Klar, *PDA Europe*
	Welcome from the Chairs	Patrick Costello, *AbbVie* Vinny Browning III, *Amgen*
OPENING PLENARY: Data Impact on Inspections		*Moderator:* **Vinny Browning III,** *Amgen*
	Use of Data in Post Approval Change Management Protocol	*EMA*
	Quality Management Maturity	*CSL Behring*
	Digital Quality Transformation: How to Efficiently Enhance Product Quality and Patient Outcomes	*Sparta Systems*
	Q&A; Discussion	
10:50	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	
SESSION 1: Quality Risk Management		*Moderator:* **Eva Urban,** *CSL Behring*
	Data-Driven Risk-Based Decision Making	*GMP Services*
	Transformation and Digitalization of the Quality Risk Management Approach to Make Knowledge Flow	*Novo Nordisk*
	ICH Q9 R1: The ®Evolution of Quality Risk Management	*Körber Pharma Consulting*
	Q&A; Discussion	
12:50	**LUNCH BREAK, POSTER SESSION & EXHIBITION**	
SESSION 2: Data Part 1		*Moderator:* **Travis Frick,** *Adverum Biotechnologies*
	Interactive Session	
	A Holistic Approach to Product Performance Management	*Abbvie*
	Smart Surveillance (S2) Analytical System	*Amgen*
	Q&A; Discussion	
15:10	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	

SESSION 3: Data Part 2		Moderator: **Patrick Costello,** *AbbVie*
	Shaping the Future of Manufacturing Quality – From Quality Metrics to Quality Management Maturity and Beyond	*St. Gallen University*
	A Digitalized Way into Submissions	*Accumulus*
	Q&A; Discussion	
	Conference Summary Day 1	*Moderation:* Patrick Costello, *AbbVie* Vinny Browning III, *Amgen*
17:15	**END OF CONFERENCE DAY 1 & NETWORKING EVENT**	

CONFERENCE AGENDA

THURSDAY, 6 OCTOBER 2022		08:00 – 17:00
08:00 – 08:50	**Quality System Interest Group: An Interactive Morning Coffee**	Eva Urban, *CSL Behring* Lothar Hartmann, *PHACT*
9:00	**Opening by the Chairs**	Patrick Costello, *AbbVie* Vinny Browning III, *Amgen*
SESSION 4: Inspections		*Moderator:* **Daniel Davis,** *GSK*
	Current Overview of GMDP Inspection Findings	*Regierungspräsidium Tübingen*
	Teachings from the Training of Inspectors and Inspector Academy Insights	*TM Pharma Group*
	Remote Regulatory Inspections: Points to Consider and the Use of Technology	*GSK*
	Q&A; Discussion	
10:40	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	
SESSION 5: Use of Data in GMP / GDP		*Moderator:* **Jette Johansen,** *Novo Nordisk*
	Sustainability: Opportunities and Challenges to Manage Regulatory GMP/GDP Inspections	*Amgen*
	Advancing Sustainable Pharma Supply Chains Through Policy & Research	*Skycell*
	Q&A; Discussion	
12:20	**LUNCH BREAK, POSTER SESSION & EXHIBITION**	
SESSION 6: Use of Data		*Moderator:* **Vinny Browning III,** *Amgen*
	Interactive Session	
	Continued Method Verification: Data-Driven Advanced Monitoring of Method Performance and Beyond	*GSK*
	Applying Quality by Design Principles and a Quality Risk Management Framework to Ensure Container Closure Integrity of a COVID-19 Vaccine Product During Ultra-Cold Chain Storage and Distribution	*Pfizer & Lighthouse Instruments*
	Q&A; Discussion	
14:40	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	

CLOSING PLENARY: Regulator Use of Data		*Moderator:* **Patrick Costello,** *AbbVie*
	Use of Real-World Data and Evidence in Europe for Regulatory Decision Making	*DKMA*
	How Regulators are Using Data to Drive Better Products and Patient Outcomes	*HPRA*
	Q&A & Final Panel Discussion with all Regulators	*Moderator:* Patrick Costello, *AbbVie*
	Chairs Conference Summary	Patrick Costello, *Abbvie* Vinny Browning III, *Amgen*
	Closing Remarks & Farewell	Falk Klar, *PDA Europe*
17:00	**END OF CONFERENCE**	

The agenda is subject to change without notice

VENUE

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SPECIAL REQUIREMENTS

If you require special assistance to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to info@pda.org.

PDA EUROPE

UPCOMING CONFERENCES AND EVENTS

FOR FURTHER INFORMATION
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www.pda.org

2022

30 Jun 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
01 JUN 2022	2022 PDA Pre-filled Syringes Workshop	Basel, Switzerland
01 JUN 2022	2022 PDA Packaging Science Workshop	Basel, Switzerland
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
08 NOV 2022	2022 PDA Visual Inspection Workshop	Berlin, Germany