2022 PDA Quality & Regulations Conference

How industry and regulators will use data to drive continuous improvement of products and better patient outcomes!

Amsterdam / The Netherlands

05-06 October 2022

Wednesday, 05 October 2022

09:00	Welcome by the Chairs	Patrick Costello, *AbbVie* Vinny Browning III, *Amgen*
Opening Plenary: Submission		**Moderator:** Vinny Browning III, *Amgen*
Submissions are a major part of our Industry and a major part of what our Regulators review to ensure our products are fit for purpose. In this session, we will hear from our Regulators and Industry on how each is applying data to submissions to streamline this process. We will also hear how this helped to get the COVID vaccines/medicines reviewed in an iterative way.		
09:10	COVID vaccines/medicines the use of data to facilitate rolling (iterative) review of applications	*EMA*
09:35	Use of Data in Post Approval Change Management Protocol	Brian Dooley, *EMA*
10:00	A Digitalized way into Submissions	Angela Currie, AstraZeneca on behalf of *Accumulus*
10:20	Q&A; Discussion	
10:50	Coffee Break, Poster Session & Exhibition	
Session 1: Quality Management Systems		**Moderator:** Daniel Davis, *GSK*
11:20	Quality Management Maturity	Mai Viholm, *CSL Behring* Eva Urban *on behalf of QMM Task Force by PDA*
11:40	Digital Quality Transformation: How to Efficiently Enhance Product Quality and Patient Outcomes	Zillery Fortner, *Sparta Systems*
12:00	Shaping the Future of Manufacturing Quality – From Quality Metrics to Quality Management Maturity and beyond	Thomas Friedli & Matteo Bernasconi, *St. Gallen University*
12:25	Q&A; Discussion	
12:55	Lunch Break, Poster Session & Exhibition	
Session 2: Quality Risk Management		**Moderator:** Evan Urban, *CSL Behring*
Quality Risk Management (QRM) has been introduced many years ago but is still a mystery and challenge for many. ICH has recently published draft guidance for revision 1 of its quality guideline Q9 on QRM. What have been the main drivers for the revision? The session will highlight what stays the same, what has changed, and which aspects have been added or gained more attention in this update, thereby helping to answer the question whether of the new revision is rather a revolution or an evolution. Another key objective will be to present the opportunities and challenges when using data as evidence to support complex decision-making within QRM and the wider PQS. One of the focus areas of the revision is clarity on risk-based decision making (RBDM). The outcome of research for a Ph.D. thesis is shared in terms of the challenges of acquiring, analyzing, interpreting, and verifying data to support RBDM and wider pharmaceutical decision-making within the manufacturing environment. The third part is the identification of the need for a transformation - maturing QRM in Novo Nordisk A/S and connecting the dots and designing a blueprint of a future state QRM approach and the path towards digitalization - how far have we come.		
13:55	Interactive Questionnaire	
14:05	Data-Driven Risk-Based Decision Making	Valerie Mulholland, *GMP Services*
14:25	Transformation and Digitalization of the Quality Risk Management Approach to Make Knowledge Flow	Michael Schousboe, *Novo Nordisk*
14:45	ICH Q9 R1: The ®Evolution of Quality Risk Management	Stefan Muench,

		Koerber Pharma
15:05	Q&A; Discussion	
15:35	Coffee Break, Poster Session & Exhibition	
Session 3: Product & Process Surveillance		**Moderator:** Jette Johansen, *Novo Nordisk*
The session will give some very good examples of how data can be used to monitor product and process performance in different ways. How a "Holistic Product Review" by use of a digital platform can be used to accelerate the decisions to ensure safe and effective medicines. How an industry-leading program has been able to tie the dots together from product complaints and adverse events, and instantaneously stitch this data with commercial, manufacturing site, quality, regulatory, and public domain data for real-time data analysis. And finally learn how a risk-based approach and statistical tools can be used for monitoring the analytical testing methods used for Quality Control providing increased proactiveness in detecting and anticipating potential testing issues, and opportunities to optimize and strengthen analytical control strategies. All in all, get inspired on how you can increase the monitoring of your process and product performance.		
16:05	A Holistic Approach to Product Performance Management	Michael Donald Grischeau, *AbbVie*
16:25	Smart Surveillance (S2) Analytical System	Peter Eskander, *Amgen*
16:45	Continued Method Verification: Data-Driven Advanced Monitoring of Method Performance and Beyond	Samantha Hawgood, *GSK*
17:05	Q&A; Discussion	
17:35	Chairs Conference Summary	**Moderation:** Patrick Costello, *AbbVie* Vinny Browning III, *Amgen*
17:45	End of Conference Day 1 & Networking Event	

Thursday, 06 October 2022

08:00 – 08:50	**Building a Great Quality Management Maturity (QMM) – An interactive morning coffee session** The interactive IG Systems session will provide the opportunity to share best practices and challenges during the establishment and implementation of a QMM model.	Eva Urban, *CLS Behring* Ghada Haddad, *Merck*
09:00	Opening by the Chairs	Patrick Costello, *AbbVie* Vinny Browning III, *Amgen*
Session 4: Inspections		**Moderator:** Daniel Davis, *GSK*
The GMP & GDP inspection landscape has changed unrecognizably following the start of the COVID pandemic and is undergoing further significant shifts. Key drivers for this have been both travel restrictions imposed on inspectors by the pandemic, and the issuance of highly impactful new regulatory requirements such as those contained in EU GMP Annex 1. During this session, we will hear from current and recent ex-regulators on where they see the current and emerging focuses of inspectorates, and how inspectors are undergoing training to meet these new challenges. The adoption of technology and new ways of working to facilitate remote inspections during the pandemic will also be discussed, together with insights on where these new types of inspections are likely to persist in the future.		
09:05	Current Overview of GMDP Inspection Findings	Alexander Kammerlocher, *Regierungspraesidium Thuebingen*
09:30	Teachings from the Training of Inspectors and Inspector Academy Insights	Tracy Moore, *TM Pharma Group*

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09:50	Remote Regulatory Inspections: Points to Consider and the Use of Technology	Alex Drapier, *GSK*
10:10	Q&A; Discussion	
10:40	Coffee Break, Poster Session & Exhibition	
Session 5: Use of Data in GMP / GDP		**Moderator:** Eva Urban, *CSL Behring*
This session starts with an overview of the current inspections landscape, will inform on hot topics and trends from the industry side, and demonstrate the pros and cons, based on practical experience, of a variety of tools used in inspections incl. virtual and hybrid. It will be demonstrated how [SR] reliance can be used to make risk-based regulatory decisions on scheduling inspections and sharing knowledge. Followed by the presentation showing options on how to reduce CO2 emissions in pharma logistics. One possibility to do that is to launch a research project that collects the data of the pharmaceutical cold chain and identifies the relevant environmental criteria such as volume, weight, and temperature excursion rates, which can then be implemented into existing frameworks. It follows a Case study of the Pfizer BioNTech COVID-19 vaccine to explain how a QRM framework was used to design appropriate studies and testing strategies for CCI of the vaccine, explains how QbD principles were applied for the generation of experimental data in a life cycle approach and how a central knowledge management framework was used to define and justify testing and control strategies in manufacturing and presents how the above approaches can be used as a general industry best practice approach.		
11:10	Sustainability: Opportunities and Challenges to Manage Regulatory GMP/GDP Inspections	Stephan Roenninger, *Amgen*
11:30	Advancing Sustainable Pharma Supply Chains Through Policy & Research	Michael Hegglin, *Skycell*
11:50	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	Michael Edey, *Pfizer* Derek Duncan, *Lighthouse Instruments*
12:10	Q&A; Discussion	
12:40	Lunch Break, Poster Session & Exhibition	
Closing Plenary: Regulator Use of Data		**Moderator:** Patrick Costello, *AbbVie*
The presenters in this session are from two of the leading regulatory authorities in the EU. These presentations will give us insights as to how regulators use data to inform their decision-making around marketing authorizations and to drive better patient outcomes.		
13:40	Interactive Questionnaire	
13:50	Use of Real-World Data and Evidence in Europe for Regulatory Decision-Making	Jesper Kjaer, *DKMA*
14:15	How Regulators Are Using Data to Drive Better Products and Patient Outcomes	Sean Barry, *HPRA*
14:40	Coffee Break, Poster Session & Exhibition	
15:10	*Coming soon*	*Coming soon*
15:35	Q&A & Final Penal Discussion	**Moderator:** Patrick Costello, *AbbVie*
16:15	Chairs Conference Summary	Patrick Costello, *Abbvie* Vinny Browning III, *Amgen*
16:25	Closing Remakes & Farewell	Falk Klar, *PDA Europe*
16:30	End of Conference Day 2	

The agenda is subject to change without notice, Speakers are invited pending confirmation!