PDA
Parenteral Drug Association

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

Time	Topic	Speaker
09:00	Welcome by the Chairs	Patrick Costello, *AbbVie* Vinny Browning III, *Amgen*
Opening Plenary: Submission		**Moderator:** Vinny Browning III, *Amgen*
09:10	Use of Data in Post Approval Change Management Protocol	*EMA*
09:35	COVID vaccines/medicines the use of data to facilitate rolling (iterative) review of applications	*EMA*
10:00	A Digitalized way into Submissions	Angela Currie, AstraZeneca / *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 ICH has recently published draft guidance for revision 1 of its quality guideline Q9 on QRM.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.

Time	Topic	Speaker
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 Münch, *Koerber Pharma*
15:05	Q&A; Discussion	
15:35	Coffee Break, Poster Session & Exhibition	

Session 3: Product & Process Surveillance		Moderator: Jette Johansen, *Novo Nordisk*
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. What data is collected and how is it used? How are metrics established? Is data gathering a manual process or is it digitally enabled? Is there room for subjectivity when interpreting data? Is the data representative of quality operations? What are the biggest success factors, challenges, and opportunities?	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, *Regierungspräsidium Thübingen*
09:30	Teachings from the Training of Inspectors and Inspector Academy Insights	Tracy Moore, *TM Pharma Group*
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	

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Session 5: Use of Data in GMP / GDP		Moderator: Eva Urban, *CSL Behring*
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*
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!