



2021 PDA Europe Quality and Regulations Conference

19-20 October 2021 | Online

A New Risk Landscape in an Evolving Quality and Regulatory Environment

Tuesday, 19 October 2021		11:00h – 18:00h CEST
11:00 Conference Opens - Exhibition and Poster Session		
12:00	Welcome from PDA	Falk Klar, <i>PDA Europe</i>
12:05	LIVE Welcome from the Chairs	Vinny Browning III, <i>Amgen</i> Karin Baer, <i>NeuroDerm</i>
12:10	Session 1 International Regulatory Updates LIVE Session Introduction <i>This session will review multiple updates from various Regulators around our new Risk Landscape in an Evolving Quality and Regulations Environment.</i>	Moderators: Vinny Browning III, <i>Amgen</i> Karin Baer, <i>NeuroDerm</i>
12:15	Update on Agency Activities	Brendan Cuddy, <i>European Medicines Agency (EMA)</i>
12:35	New Regulatory Initiatives in the UK for Innovative Medicines - Innovative Licensing and Access Pathway (ILAP) & ‘Point of Care’ (POC) Manufacturing for Personalized Medicines	Philip Rose, <i>Medicines and Healthcare products Regulatory Agency (MHRA)</i>
12:55	Updates and a Perspective on ICH Q12 Implementation in Japan	Yasuhiro Kishioka, <i>PMDA</i>
13:15	LIVE Panel Discussion	Panelists: Brandan Cuddy, <i>EMA</i> Philip Rose, <i>MHRA</i> Yasuhiro Kishioka, <i>PMDA</i> Moderators: Vinny Browning III, <i>Amgen</i> Karin Baer, <i>NeuroDerm</i>
14:00 Coffee Break, Exhibition & Poster Session		



2021 PDA Europe Quality and Regulations Conference

19-20 October 2021 | Online

A New Risk Landscape in an Evolving Quality and Regulatory Environment

15:00	Session 2 International Perspectives: Remote Inspections LIVE Session Introduction <i>The restrictions on travel associated with COVID pandemic resulted in greater use of remote/virtual GMP inspections. This session explores regulator and industry perspectives on the experiences and learnings from alternatives to on-site inspections and introduces the PDA Points to Consider paper on Remote Inspections.</i>	Moderators: Graham Cook, <i>Pfizer</i> Glenn Wright, <i>PDA</i>
15:05	Hosting Remote Inspections by Russian and EU Regulators	Elizabeth Meyers, <i>Amgen</i>
15:25	Perspective of the Russian GMP Inspectorate	Vladislav Shestakov, <i>State Institute of Drugs and Good Practices</i>
15:45	Conducting Remote GMP Inspections of API Manufacturers in Real Time	Thomas Hecker, <i>EDQM</i>
16:10	Coffee Break, Exhibition & Poster Session	
16:45	New Opportunities and Challenges in Conforming with Compliance in Inspections	Stephan Roenninger, <i>Amgen</i>
17:05	Industry Perspective: PDA PTC on Remote Inspections	Eva Urban, <i>CSL Behring</i>
17:25	LIVE Panel Discussion, Q&A	Panelists: Elizabeth Meyers, <i>Amgen</i> Thomas Hecker, <i>EDQM</i> Stephan Roenninger, <i>Amgen</i> Eva Urban, <i>CSL Behring</i> Moderators: Graham Cook, <i>Pfizer</i> Glenn Wright, <i>PDA</i>



2021 PDA Europe Quality and Regulations Conference

19-20 October 2021 | Online

A New Risk Landscape in an Evolving Quality and Regulatory Environment

18:00	End of Conference Day 1	
Wednesday, 20 October 2021 11:00h – 17:00 CEST		
11:00	Conference Opens - Exhibition and Poster Session	
12:00	Session 3 Quality & Regulations in Times of a Pandemic LIVE Session Introduction	Moderators: Patrick Costello, <i>AbbVie</i> Travis Frick, <i>Istari Oncology</i>
12:05	FDA Guidance Update: COVID-Related Quality Policies	Ashley Boam, <i>US FDA</i>
12:25	USP's Evolving Approaches to Compendial Standards	Fouad Atouf, <i>USP</i>
12:45	Moving towards Compliance to MDR Article 117 – Many Unanswered Questions	Bettine Boltres, <i>WEST</i>
13:05	Handling Out of Specification Test Results	Jens Ohnesorge, <i>Roche</i>
13:25	LIVE Panel Discussion, Q&A	Panelists: Ashley Boam, <i>US FDA</i> Fouad Atouf, <i>USP</i> Bettine Boltres, <i>WEST</i> Jens Ohnesorge, <i>Roche</i> Moderators: Patrick Costello, <i>AbbVie</i> Travis Frick, <i>Istari Oncology</i>
14:00	Coffee Break, Exhibition & Poster Session	



2021 PDA Europe Quality and Regulations Conference

19-20 October 2021 | Online

A New Risk Landscape in an Evolving Quality and Regulatory Environment

15:00	Session 4 Quality Risk Management LIVE Session Introduction <i>This session will outline Quality Risk Management covering the strategical point of view, touching upon the areas of changes of ICH Q9 as per the ICH Q9 Concept paper; providing some background, elaborating informed decision making, level of formality of risk management and will also show case studies and practical examples.</i>	Moderators: Eva Urban, <i>CSL Behring</i> Karin Baer, <i>NeuroDerm</i>
15:05	Seeking the Diamonds – From QRM to PQS Decision-Making	Valerie Mulholland, <i>GMP Services Ltd</i>
15:25	Utilization of A Quality Risk Management (QRM) Approach	Janmeet Anant, <i>Merck KGaA</i>
15:45	A Holistic Approach to Virus Risk Assessment and Controls in A Drug Substance Ballroom Facility	Joe Jerkins, <i>Genentech/Roche</i>
16:05	Coffee Break, Exhibition & Poster Session	
16:25	LIVE Q&A, Discussion	Panelists: Valerie Mulholland, <i>GMP Services Ltd</i> Janmeet Anant, <i>Merck KGaA</i> Joe Jerkins, <i>Genentech</i> Moderators: Eva Urban, <i>CSL Behring</i> Karin Baer, <i>NeuroDerm</i>
16:55	LIVE Conference Closing & Summary	Vinny Browning III, <i>Amgen</i> Karin Baer, <i>NeuroDerm</i>
17:00	Thank You Remarks and Farewell	Falk Klar, <i>PDA Europe</i>

Agenda is subject to change without notice, all times are listed in CEST