PDA Manufacturing Meets Legislation Workshop 2024
Berlin, Germany
04-06 September 2024
Change Hub, Hardenbergstraße 32, 10623 Berlin

Agenda

Wednesday, 04 September 2024 — 13:00 - 17:00 CEST

Module 1: Preparation for EMA Inspectors Working Group Dialogue		**Moderator:** *RAQAB Representative*
13:00	Welcome	Falk Klar, *PDA*
	Introduction to Industry-Regulators Interaction	*RAQAB Representative*
	Presentation of the Submitted Topics Workshop Speed Discussions	*All Topic submitters*
15:15	**Coffee Break**	

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	Discussion Round with Readout	*All Topic Submitters*
	Summary of Selected Topics	**Moderator:** RAQAB Representative
17:00	End of Workshop Day 1	
Thursday, 05 September 2024		**09:00 - 16:45 CEST**
Module 2: Impact of Planned PFAS Ban on the Pharmaceutical Industry in Europe		**Moderator:** Ana Kuschel, *WEST* Ankur Kulshrestha, *BMS*
09:00	EFPIA White Paper on PFAS Ban/Substitution	Louise Loughran, *Eli Lilly and Company*
	Overview of the PFAS Situation for their Use in Pharmaceutical Filtration, Opportunities and Risks	Alexander Mitropoulos, *Merck*
	Considerations for Early-Stage Testing of Chemicals for PFAS Replacement	Dieter Hennecke, *Fraunhofer Institut*
10:30	**Coffee Break**	
	Flipchart Activity on PFAS Risk Assessment	*Invited Speakers*
12:00	**Lunch Break**	

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Module 3: Challenges and Opportunities in Pharmaceutical Manufacturing in Europe		**Moderator:** Veronique Davoust, *Pfizer*
13:00	EDQM Remote Inspections	Oisin Daly, *EDQM*
	Challenges of a Public Affairs Perspective – Values, Mission, and Patient Centricity	*Merck Public Affairs*
	Innovative Manufacturing Approaches in Europe: From Idea to Implementation	Ursula Busse, *Tigen Pharma*
	PDA's Initiative for Early Career Professionals	Bettine Boltres, *WEST*
	Challenges and Opportunities	*Invited Speaker*
14:45	**Coffee Break**	
	Road to Resilience: A Young Professional's Journey	Miriam Kremer van der Kamp, *Vils*
	Running the Pharmaceutical Packaging Race	Ana Kuschel, *WEST*
	Panel Discussion	
16:45	**End of Workshop Day 2**	

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Friday, 06 September 2024		**09:00 - 11:15 CEST**
Module 4: Overview of the Current Changes in the EU Regulatory Framework *This session will provide an overview of the hot topics changing in the EU legislative framework impacting manufacturing, quality, and supply.*		**Moderator:** Stephan Rönninger, *Amgen*
09:00	**Welcome Coffee Break**	
	Pharmaceutical Manufacturing in the Regulatory Framework	Stephan Rönninger, *Amgen*
	Overview of Upcoming Regulatory Changes Relating to Sustainability	Marion Briggs, *Airfield Consulting*
	Panel Discussion ***General Pharma Legislation*** *Impact on CMC, manufacturing, environmental risk assessment, inspections, imported products, and supply.* ***'License to Operate'*** *Under that term, the requirements for environmental control and sustainability are managed* ***Drug Shortage Prevention*** *While companies and marketing authorization holders follow basic principles implementation measures by individual EU Member States and other countries may benefit from a holistic harmonized approach and identifying the real root causes.*	**Moderator:** Stephan Rönninger, *Amgen*
	Key Messages: Call to Action	**Moderator:** Stephan Rönninger, *Amgen*

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	Farewell	Falk Klar, *PDA*
11:15	**End of Workshop**	

The agenda is subject to change.