PDA ICH Q5A R2 Essentials: Training and Practical Applications Workshop 2025

Agenda

Monday, 23 June

CEST Daylight Time (UTC +2:00)

09:00 – 09:05	**Welcome and Introduction** **Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association* **Alison Armstrong PhD** Senior Director, Global Head Scientific and Regulatory Consultancy *Merck KgAG*
09:05 – 09:20	**Navigating ICH Q5A R2: From Theory to Practice** **Andy Bailey PhD**, CEO, *ViruSure GmbH*
09:20 – 10:35	**Introduction of New Modalities and Impact of Virus Safety** **Moderator: Alison Armstrong PhD**, Senior Director, Global Head Scientific and Regulatory Consultancy, *Merck KgAG*

09:20 – 09:35	**ICH Q5AR2 Annex 6: Genetically Engineered Viral Vectors and Viral Vector–Derived Products** • **Anne Stokes PhD**, , *GSK*
09:35 – 09:50	**Minimizing Viral Risk: New Analytical Technologies, Testing Approaches** • **Marie Murphy PhD**, , *Eli Lilly & Co. Ireland*
09:50 – 10:05	**Questions on Applications of New Modalities and Testing** • **Arifa S Khan PhD**, Supervisory Microbiologist, DVP, OVRR, CBER, *U.S. FDA*
10:05 – 10:35	**Open Discussion**

10:35 – 11:05	**Coffee Break**
11:05 – 13:00	**Continuous Biomanufacturing** **Moderator: Johannes Bluemel PhD**, Head of Virus Safety Section, *Paul-Ehrlich-Institut*

11:05 – 11:25	**Continuous Biomanufacturing – ICH Q5A (R2) Training Materials** • **Marie Murphy PhD**, , *Eli Lilly & Co. Ireland*
11:25 – 11:45	**Viral Inactivation in Continuous Mode: Advancing Innovation Through Engagement With Regulatory Agencies** • **Ushma Mehta MS**, Senior Regulatory Expert, *MilliporeSigma*
11:45 – 12:05	**Continuous Virus Filtration Validation Strategies: Impact of ICH Q5A (R2)** • **Julie Kozaili** , Principal Scientist, *Asahi Kasei*

	12:05 – 13:00	**Open Discussion**
13:00 – 14:00	**Lunch Break**	
14:00 – 15:15	**Viral Clearance** **Moderator: David R. Van Houte PhD**, Senior Manager - QC Virology, *Regeneron Pharmaceuticals*	
	14:00 – 14:20	**Claiming Virus Reduction from Prior Knowledge** • **Johannes Bluemel PhD**, Head of Virus Safety Section, *Paul-Ehrlich-Institut*
	14:20 – 14:40	**TEM in Viral Safety: Bridging a Century of Virus Imaging with Modern Testing Standards** • **Ashley Stephen Layland** , Project Director, *neotem Bioanalytics-IIT GmbH*
	14:40 – 15:15	**Discussion Round**
15:15 – 15:45	**Coffee Break**	
15:45 – 16:30	**Panel Discussion** **Moderator: Simone Olgiati PhD**, Head of Molecular Biology Technology & Innovation, *Merck*	
16:30 – 16:50	**Summary of the Workshop and Take-Home Messages** **Alison Armstrong PhD**, , *Merck KGaA*	
16:50 – 17:00	**End of Workshop and Farewell**	