

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

Agenda

Monday, 23 June

CEST Daylight Time (UTC +2:00)

Welcome and Introduction

09:00 – 09:05

Falk Klar PhD, General Manager, Vice President Europe, *Parenteral Drug Association*

Alison Armstrong PhD Senior Director, Global Head Scientific and Regulatory Consultancy *Merck KgAG*

Navigating ICH Q5A R2: From Theory to Practice

09:05 – 09:20

Andy Bailey PhD, CEO, *VirusSure GmbH*

Introduction of New Modalities and Impact of Virus Safety

Moderator: Alison Armstrong PhD, Senior Director, Global Head Scientific and Regulatory Consultancy, *Merck KgAG*

ICH Q5AR2 Annex 6: Genetically Engineered Viral Vectors and Viral Vector–Derived Products

09:20 – 09:35

- **Anne Stokes PhD**, , *GSK*

Minimizing Viral Risk: New Analytical Technologies, Testing Approaches

09:35 – 09:50

- **Marie Murphy PhD**, , *Eli Lilly & Co. Ireland*

Questions on Applications of New Modalities and Testing

09:50 – 10:05

- **Arifa S Khan PhD**, Supervisory Microbiologist, DVP, OVR, CBER, *U.S. FDA*

10:05 – 10:35

Open Discussion

10:35 – 11:05

Coffee Break

Continuous Biomanufacturing

Moderator: Johannes Bluemel PhD, Head of Virus Safety Section, *Paul-Ehrlich-Institut*

Continuous Biomanufacturing – ICH Q5A (R2) Training Materials

11:05 – 11:25

- **Marie Murphy PhD**, , *Eli Lilly & Co. Ireland*

Viral Inactivation in Continuous Mode: Advancing Innovation Through Engagement With Regulatory Agencies

11:25 – 11:45

- **Ushma Mehta MS**, Senior Regulatory Expert, *MilliporeSigma*

Continuous Virus Filtration Validation Strategies: Impact of ICH Q5A (R2)

11:45 – 12:05

- **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, <i>Regeneron Pharmaceuticals</i>	
	Claiming Virus Reduction from Prior Knowledge	
	14:00 – 14:20	• Johannes Bluemel PhD , Head of Virus Safety Section, <i>Paul-Ehrlich-Institut</i>
	TEM in Viral Safety: Bridging a Century of Virus Imaging with Modern Testing Standards	
	14:20 – 14:40	• Ashley Stephen Layland , Project Director, <i>neotem Bioanalytics-IIT GmbH</i>
	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, <i>Merck</i>	
16:30 – 16:50	Summary of the Workshop and Take-Home Messages	
	Alison Armstrong PhD , , <i>Merck KGaA</i>	
16:50 – 17:00	End of Workshop and Farewell	