

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

As a part of the PDA Innovative Therapies Summit 2025

Gothenburg, Sweden

23 June 2025

Agenda Preview

Monday, 23 June 2025		
09:00	Welcome and Introduction	Falk Klar, <i>PDA Europe</i> Alison Armstrong, <i>Merck</i>
	Navigating ICH Q5A R2: From Theory to Practice	<i>ViruSure</i>
Topic: Introduction of New Modalities and Impact of Virus Safety		Moderator: Alison Armstrong, <i>Merck</i>
	EU GMP Annex 6 – Genetically Engineered Viral Vectors and Viral Vector-Derived Products	Anne Stokes, <i>GSK</i> <i>PhRMA Lead for the Q5A update</i>
	Minimizing Viral Risk: New Technologies, Testing Approaches	Marie Murphy, <i>Eli Lilly and representing EFPIA</i>
	New Cell Lines: Most Challenging Questions	Arifa Khan, <i>US FDA</i>
	Panel Discussion	
10:30	Coffee Break	

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Topic: Continuous Biomanufacturing		Moderator: Johannes Bluemel, <i>Paul-Ehrlich-Institut</i>
	Title To Be Announced	<i>Roche</i>
	Title To Be Announced	<i>Invited Speaker</i>
Discussion Round		
12:00	Lunch Break	
Topic: Viral Clearance		Moderator: David van Houte, <i>Regeneron</i>
	Claiming Virus Reduction from Prior Knowledge	Johannes Blümel, <i>Paul-Ehrlich-Institut</i>
	TEM in Viral Safety: Bridging a Century of Virus Imaging with Modern Testing Standards	Ashley Stephen Layland, <i>eotem Bioanalytics-IIT</i>
Discussion Round		
14:30	Coffee Break	
	Interactive Session	Moderator: Simone Olgiati, <i>Merck</i>
	Summary of the Workshop and Take-Home Messages	Alison Armstrong, <i>Merck</i>

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		Falk Klar, PDA Europe
16:50	End of Workshop and Farewell	

The program is subject to changes.