

	 PharmaLab Analytics ■ Bioanalytics ■ Microbiology Congress & Exhibition Düsseldorf, 24-26 November 2025		
Time	25 November 2025 Bioassays/Potency Assays – Regulatory Requirements, Development and Routine Use		Time
09:00 h	Welcome and Introduction (at the Plenum)		09:00 h
09:15 h	KEYNOTE: AI in Pharma: The Hype, The Hope, The How Dr Marcel Franke, Senior Scientist Predictive Formulation, Process Solutions/Upstream & Process Materials R&D Merck Life Science		09:15 h
09:30 h			09:30 h
09:45 h			09:45 h
10:00 h	Coffee break / Conference Exhibition		10:00 h
10:15 h			10:15 h
10:30 h			10:30 h
10:45 h	Key Aspects of Assay Control throughout the Analytical Lifecycle Dr Sonja Klingelhöfer, Richter Biologics		10:45 h
11:00 h	Reference Standard Qualifications and Re-Evaluations for Potency Assays Dr Pieta Boon & Jos Weusten, MSD		11:00 h
11:15 h			11:15 h
11:30 h			11:30 h
11:45 h	Bioassay Primer: Model-Based Confidence Interval Effects Dr Florian Müller-Sallanz, Stegmann Systems		11:45 h
12:00 h	Lunch Break / Conference Exhibition		12:00 h
12:15 h			12:15 h
12:30 h			12:30 h
12:45 h			12:45 h
13:00 h			13:00 h
13:15 h			13:15 h
13:30 h	Bioassay Relevant Texts in the Ph. Eur. as well as the Potency Strategy in the Ph. Eur. for mAbs Dr Solène Le Maux, EDQM		13:30 h
13:45 h			13:45 h
14:00 h			14:00 h
14:15 h	A (Former) CDER Reviewer's Perspective on Potency Assays Gerry Feldman, formerly FDA		14:15 h
14:30 h			14:30 h
14:45 h			14:45 h
15:00 h	Coffee Break / Conference Exhibition		15:00 h
15:15 h			15:15 h
15:30 h			15:30 h
15:45 h	Challenges in Optimization and Validation of Potency Assays in a State Batch Testing Laboratory Dr Lilija Miller, Paul Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines		15:45 h
16:00 h			16:00 h
16:15 h			16:15 h
16:30 h	Case Study: Validation and Bridging of a Flow Cytometry Potency Assay for a Therapeutic Monoclonal Antibody Dr Frances Reichert, Eurofins		16:30 h
16:45 h	Of Mice and (Wo)Men Simone Tomaschek, Roche		16:45 h
17:00 h			17:00 h
17:15 h			17:15 h
17:30 h	Discussion Day 1		17:30 h
17:45 h			17:45 h
18:00 h			18:00 h

		
Time	26 November 2025	Time
	Bioassays/Potency Assays – Regulatory Requirements, Development and Routine Use	
09:00 h	Welcome and Introduction (at the Plenum)	09:00 h
09:15 h	KEYNOTE: Phage Therapy: History, Current Challenges and Perspectives Dr Frédérique Vieville, CEO, 5QBD-Biotech	09:15 h
09:30 h		09:30 h
09:45 h		09:45 h
10:00 h	Coffee break / Conference Exhibition	10:00 h
10:15 h		10:15 h
10:30 h		10:30 h
10:45 h	Case Study of an Enhanced Development for a Bioassay Dr Simon Anderhub, Novartis	10:45 h
11:00 h		11:00 h
11:15 h	"Where Fat and Sugar Meet" - Setup of a Glucose Uptake Assay in Differentiated Adipocytes Dr Ella Rosenzweig, Vela Labs	11:15 h
11:30 h		11:30 h
11:45 h	Advancing Bioassay Technologies with NanoBiT Split Luciferase Dr Jamison Grailer, Promega	11:45 h
12:00 h		12:00 h
12:15 h		12:15 h
12:30 h	Lunch Break / Conference Exhibition	12:30 h
12:45 h		12:45 h
13:00 h		13:00 h
13:15 h		13:15 h
13:30 h		13:30 h
13:45 h	Combination of Cell-based Potency Assay with Digital Droplet PCR® Readout as Innovative and New Methodology for Characterization of RNAi Therapeutic Qfitlia® (Fitusiran) Christine Graf, Sanofi	13:45 h
14:00 h		14:00 h
14:15 h	Development and Optimization of the Infectious Titer Assay (TCID50) for Recombinant AAV Annemie Wielant, UCB	14:15 h
14:30 h		14:30 h
14:45 h	A Case Study on the Challenges of Establishing a Robust Cell-based Bioassay for Plasmid DNA Potency Determination Dr Thomas Danielsen, Novo Nordisk	14:45 h
15:00 h		15:00 h
15:15 h	Coffee Break / Conference Exhibition	15:15 h
15:30 h		15:30 h
15:45 h		15:45 h
16:00 h	Making Cell-Based Potency Assays Work Better for QC: A Simpler, Stronger Solution Peter Wolff, AGC Biologics	16:00 h
16:15 h		16:15 h
16:30 h	Ensuring Consistency in Bioassay Method Transfer: Strategies for Overcoming Variability Jessica Weaver, BioAgilytix	16:30 h
16:45 h		16:45 h
17:00 h	Case Study on the Development of a Cell-based Assay Morgane Gesquière, UCB	17:00 h
17:15 h		17:15 h
17:30 h	Final Discussion	17:30 h
17:45 h		17:45 h
18:00 h		18:00 h