

	Version dated 30 September 2025 Subject to change	
Time	25 November 2025	Time
	Cell and Gene Therapies/ ATMP - Quality and Safety	
09:00 h	Welcome and Introduction (at the Plenum)	09:0
09:00 II	Welcome and introduction (at the Fieldin)	09:0
09:30 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	09:3
09:45 h		09:4
10:00 h	Coffee break / Conference Exhibition	10:0
10:15 h		10:1
10:30 h		10:
10:45 h	Update on Anmes in the Ph. Eur. Dr. Calège Le Mouy, EDOM	10:
11:00 h		11:
11:15 h	Understanding of Analytical Critical Quality Attributes (CQAs) for Viral Vector Characterization in Gene Therapy	11:
11:30 h	Dr Maribel Navarro, Kymos Group	11:
11:45 h	Strategy for Potency Determination of Gene Therapy Products	11:
12:00 h	Dr Ulrike Herbrand, Charles River Laboratories	12:
12:15 h		12:
12:30 h	Lunch Break / Conference Exhibition	12:
12:45 h		12:
13:00 h		13:
13:15 h		13:
13:30 h		13:
13:45 h		13:
14:00 h	High-Throughput Single-Cell Potency Assays for Cell Therapy Development Using Droplet Microfluidics Dr Stephanie van Loo, Livedrop	14:
14:15 h	or occurrence variables and a constant of the	14:
14:30 h		14:
	Call and Gana Therany COA Analysis using Mass Spactromatry	14:
15:00 h	Dr Daniel Waldera-Lupa, Protagene	15:
15:15 h		15:
15:30 h	Coffee Break / Conference Exhibition	15:
15:45 h	Office Breaky Conference Exhibition	15:
16:00 h		16:
	Optimization of Analytical Methods for Engineered Cell Therapy Products: Lessons Learned Dr David Svec & Dr Jan Blecha, SCTbio	16:
16:30 h		16:
16:45 h		16:
	Validation of VCN Determination by dPCR on a Retroviral CAR-T Cell Product in Compliance with ICH Q14 and Q2(R2)	
	Dr Katy Haussmann, Charité & Dr Daniel Lindemeier, Labor LS	17:
17:15 h		17:
17:30 h	h Discussion Day 1	17:
17:45 N		17:4



	Version dated 01 October 2025 Subject to change	
Time	26 November 2025	Time
	Cell and Gene Therapies/ ATMP - Quality and Safety	
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	Coffee break / Conference Exhibition	09:45 h
10:00 h		10:00 h
10:15 h 10:30 h		10:15 h
10:45 h		10:30 h
11:00 h	Developing Control Strategies for Off-the-shelf Allogenic Cell Therapy Products Dr Steven Braem, 3D-PharmXchange	10:45 h
11:15 h		11:00 h
11:30 h		11:15 h
	Considerations of Viral Safety Strategies for Cell Therapies – A Suggested Approach for What to Include in Viral Safety Packages for Cell	11:30 h
	Therapies Dr Kerstin Brack, CRL	11.4511
12:00 h		12:00 h
12:15 h	Lunch Break / Conference Exhibition	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		13:30 h
13:45 h	Avoiding Common Sterility Testing Compliance Gaps and Regulatory Observations During ATMP Sterility Testing Marsha Steed, Steed MicroBio LLC	13:45 h
14:00 h		14:00 h
14:15 h		14:15 h
14:30 h		
1.4:45 h	Enhancing Microbiological Quality Control with Ready-to-Use Microorganisms	14:30 h
	Dr Megha Bajaj, bioMérieux	14:45 h
15:00 h		15:00 h
15:15 h		15:15 h
15:30 h		15:30 h
15:45 h		15:45 h
16:00 h	How to Build a Digitalized End-to-End Process for Environmental Monitoring for ATMPs Release	16:00 h
	Johannes Oberdörfer, Rapid Micro Biosystems & Willem Dullaers, Lonza	16:15 h
16:30 h	Willetti Dullaers, Lotiza	16:30 h
16:45 h		
	The New Guideline on ATMPs and Further Regulatory Update on ATMPs	16:45 h
	Dr Sabine Hauck, dequra pharma consult	17:00 h
17:15 h		17:15 h
17:30 h	Final Discussion	17:30 h
17:45 h		17:45 h