



2024 PDA Advanced Therapy Medicinal Products Conference
Amsterdam, The Netherlands
Next steps in ATMPs and beyond
24-25 June 2024
Agenda Preview

Monday, 24 June 2024

9:00	Welcome and Introduction	Falk Klar, <i>PDA Europe</i>
	Welcome from the Co-Chairs	Renske ten Ham, <i>University Medical Center Utrecht</i> Richard Denk, <i>SKAN</i>
Opening Plenary		
	Keynote: 7 Things I Wish I Knew Before Undergoing Gene Therapy	<i>Patient Advocate</i>
	EMA's Experience in the Development Support and Approval of Gene Therapy Medicinal Products	<i>EMA</i>
	Enhancing Strategic Decision-Making for ATMP Development & Commercialization: The Role of Supply Chain Business Intelligence	<i>F. Hoffmann-La Roche</i>
	Q&A, Discussion	
11:00	Networking Coffee Break, Poster Session & Exhibition	
Session 1: Challenges in Manufacturing		
	The Challenges of the Innovative Exosomes-based Therapies – Case Study	<i>EXO Biologics</i>
	'Spilling the Tea' on Leaks in Autologous CAR T Manufacturing	<i>Bristol Myers Squibb</i>
	Visual Inspection & Particle Life Cycle Management in CGT Products - Same, Same but Different?	<i>Clear Solutions Laboratories & Takeda</i>



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	Q&A, Discussion	
13:00	Networking Lunch Break, Poster Session & Exhibition	
13:40	LIVE Guided Poster Walk Engage with our Poster Presenters in our Exhibition Hall	
Session 2: From Development to Commercialization		
	Interactive Questionnaire Session	<i>Via Mentimeter</i>
	Treatment with Tumor-Infiltrating Lymphocytes (TILs) for Patients with Advanced Melanoma: From a Randomized Phase 3 Trial in Academia towards Marketing Authorization	<i>Netherlands Cancer Institute / Antoni van Leeuwenhoek Hospital</i>
	Decentralizing CAR-T Production: Proof of Concept Network Experience with an Academic CAR-T	<i>IDIBAPS hospital clinic Barcelona</i>
	Decentralized Manufacturing of Autologous ATMPs: How Technology Innovation Fosters Regulatory Compliance	<i>Tigen Pharma</i>
	Q&A, Discussion	
15:50	Networking Coffee Break, Poster Session & Exhibition	
Session 3: Quality Control		
	Addressing the Challenges: Alternative Methods for ATMP Analytics Testing	<i>Merck</i>
	Viral Control Strategy for Allogeneic Cell Therapy	<i>Sanofi</i>
	Challenges in Developing a Change Control System for an ATMP Manufacturing Site	<i>Kite Pharma</i>
	Q&A, Discussion	



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17:50	End of Conference Day 1 & Networking Event	
Tuesday, 25 June 2024		
9:00	Welcome to Day 2	Renske ten Ham, <i>University Medical Center Utrecht</i> Richard Denk, <i>SKAN</i>
Session 5: Regulatory Session		
	Navigating Regulatory Challenges: Insights from Developing ATMPs through GMP/GDP/GCP	<i>PMS Process Management System</i>
	USP Microbiology Updates on RMM for Short Life Products	<i>Steed MircroBio LLC</i>
	<i>Title to be announced</i>	<i>Paul-Ehrlich Institut</i>
	Q&A, Discussion	
10:35	Networking Coffee Break, Poster Session & Exhibition	
Session 6: New Technologies		
	One-Step Instant MSC Product Accompanying Autologous Chondron Transplantation for Focal Articular Cartilage Lesions of the Knee: Preliminary Results of a Cross-Over Randomized Controlled Trial	<i>UMC Utrecht</i>
	How AI Can Transform ATMP Development	<i>Blackfin BioPharma Advisors</i>
	Q&A, Discussion	



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12:15	Networking Lunch Break, Poster Session & Exhibition	
Closing Plenary		
	Interactive Questionnaire Session	<i>Via Mentimeter</i>
	Points to Consider for Classification, Manufacture, and Control of Plasmids and Vectors Used in ATMP Production	<i>Valsource</i>
	Inspections of ATMP Production Sites and Hospital Exemption Applications	<i>Health and Youth Care Inspectorate</i>
14:10	Networking Coffee Break, Poster Session & Exhibition	
	Passport Raffle via PDA Europe	
	Fireside Chat: Swissmedic Q&A Document on EU GMP Annex 1 and Requirements for ATMPs	<i>Swissmedic & SKAN</i>
	Closing Panel Discussion Join our Discussion with Experts from the Industry and Regulatory	
	Co-Chairs Conference Summary	Renske ten Ham, <i>University Medical Center Utrecht</i> Richard Denk, <i>SKAN</i>
	Closing Remarks & Farewell	Falk Klar, <i>PDA Europe</i>
16:10	End of Conference	

The agenda is subject to change without notice, Speakers are invited pending confirmation.