

**Parenteral
Drug
Association®**

Connecting
People, Science
and Regulation®

PDA Advanced Therapy Medicinal Products Conference 2025

Gothenburg, Sweden

The Renaissance of Medicine: ATMPs and Maturing Perspectives

26-27 June 2025

Agenda Preview

Thursday, 26 June 2025

| | | |
|---------------------------------------|--|--|
| 9:00 | Welcome and Introduction | Falk Klar, PDA Europe |
| | Welcome from the Co-Chairs | Renske ten Ham, University Medical Center Utrecht & Ryan Murray, ValSource |
| Opening Plenary | | |
| | How the Past Can Advance the Future | Arcadis |
| | Future Directions in Cell Therapy Manufacturing and Enablement | L.E.K. Consultants |
| | Reclaim the C's: Feasibility of Recycling Plastic Waste During ATMP Production | Lund University |
| Plenary Discussion | | |
| 11:15 | Coffee Break, Poster Session & Exhibition | |
| Speed Session 1: Manufacturing | | |
| | Demonstrating Analytical Comparability for Complex Manufacturing Process Changes: Lessons Learned from Technical and Regulatory Perspectives | Cabaletta Bio |
| | Quality Considerations in a Decentralized CAR T Manufacturing Model | Galapagos |

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| Preventing Cross-Contamination During Manufacturing of ATMPs | | SKAN |
| <i>Title to be announced</i> | | Speaker invited |
| Q&A, Discussion | | |
| 12:55 | Lunch Break, Poster Session & Exhibition | |
| 13:40 | LIVE Guided Poster Walk Engage with our Poster Presenters in our Exhibition Hall | |
| Session 2: Regulatory Updates | | |
| Interactive Questionnaire Session | | Via Mentimeter |
| <i>Title to be announced</i> | | Sweden Agency |
| <i>Title to be announced</i> | | Regulatory Speakers invited |
| Regulation on Substances of Human Origin (SoHo): Implications for ATMP Development | | Osakidetza-Basque Health Service |
| Q&A, Discussion | | |
| 16:05 | Coffee Break, Poster Session & Exhibition | |
| Session 3: Clinical Perspective | | |
| A Patient's Journey: Life Before, During, and After Gene Therapy | | Patient Advocate |

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| <i>Title to be announced</i> | | <i>Speaker invited</i> |
| Steering Innovation to Clinical Success: The Development of a Fully Personalized Dendritic Cell Vaccine for Pediatric High-Risk Solid Tumors | | <i>Masaryk Univerzity, Faculty of Medicine, CREATIC CoE</i> |
| Q&A, Discussion | | |
| 18:10 | End of Conference Day 1 & Networking Event | |
| Friday, 27 June 2025 | | |
| 8:30 | Collaboration or Competition? The Nordic Model in ATMP Innovation | <i>Cellerator – Novo Nordisk Foundation & CCRM Nordic & Centre for Advanced Cell Therapy ACT</i> |
| Welcome to Day 2 | | <i>Renske ten Ham, University Medical Center Utrecht & Ryan Murray, ValSource</i> |
| Session 4: Quality, Safety, and Efficacy | | |
| Is That a Particle? Establishing a Particle Control Strategy in Cell Therapy | | <i>Bristol Myers Squibb</i> |
| Developing and Transferring Potency Assays for CGTs: Strategies for Success | | <i>WuXi Advanced Therapies</i> |
| <i>Title to be announced</i> | | <i>Speaker invited</i> |

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Q&A, Discussion

10:30 Coffee Break, Poster Session & Exhibition

Session 5: Manufacturing Challenges

ATMP Material Classification, Associated Framework for Development of Science & Risk Based Approach

Genentech

AAV Process Intensification: Focus on Upstream Critical Process Parameters

Merck

Viral Safety of Cell Therapy Products

Merck KGaA on behalf of BioPhorum

Q&A, Discussion

12:30 Lunch Break, Poster Session & Exhibition

Closing Plenary

Fireside Chat on Centralized vs. Decentralized ATMP Manufacturing

EMA & MEB & SKAN

Moving Drug Discovery Through the Valley of Despair: From Struggles to Solutions

GSAP

Plenary Discussion

14:35 Coffee Break, Poster Session & Exhibition

Passport Raffle via PDA Europe

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Best Poster Presentation

Interactive Round Table Session

Co-Chairs Conference Summary

Renske ten
Ham, University Medical
Center Utrecht &
Ryan Murray, ValSource

Closing Remarks & Farewell

Falk Klar, PDA Europe

16:35

End of Conference