



Agenda

PDA Advanced Therapy Medicinal Products Conference 2025

Thursday, 26 June

09:00 – 09:05

Welcome and Introduction

Committee Member: Falk Klar, PhD, General Manager, Vice President Europe, *Parenteral Drug Association*

09:05 – 09:15

Welcome from the Co-Chairs

09:15 – 11:15

Opening Plenary

Moderator: Ryan Murray, MS, Senior Consultant, *ValSource, Inc.*

09:15 – 09:40

How the Past Can Advance the Future

Presenter: Stephen Judd, BSc, MSc, CEng MIChemE, MIEI, Process SME Biologics / Cell & Gene Therapy, *DPS Group*

09:40 – 10:05

Future Directions in Cell Therapy Manufacturing and Enablement

Presenter: Tom Bell

10:05 – 10:30

Reclaim the C's: Feasibility of Recycling Plastic Waste During ATMP Production

10:30 – 11:15

Plenary Discussion

Moderator: Ryan Murray, MS, Senior Consultant, *ValSource, Inc.*

Panelist: Stephen Judd, BSc, MSc, CEng MIChemE, MIEI, Process SME Biologics / Cell & Gene Therapy, *DPS Group*

Panelist: Tom Bell

11:15 – 11:45

Networking Coffee Break, Poster Session & Exhibition

11:45 – 14:10



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Speed Session 1: Manufacturing

Moderator: Dayue Chen, PhD, Head of Cell Therapy Technical Development, *Genentech, Inc.*

11:45 – 11:55

Demonstrating Analytical Comparability for Complex Manufacturing Process Changes: Lessons Learned from Technical and Regulatory Perspectives

Speaker: Houman Dehghani, PhD, Vice President, *Cabaletta Bio*

11:55 – 12:05

Quality Considerations in a Decentralized CAR T Manufacturing Model

Speaker: Jason Treese, Global Head of Quality, *Galapagos*

12:05 – 12:15

Preventing Cross-Contamination During Manufacturing of ATMPs

Speaker: Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

12:15 – 12:25

Title to be announced

Presenter: Darius Pillsbury, Senior Consultant, *ValSource, Inc.*

12:25 – 12:55

Q&A Discussion

Moderator: Dayue Chen, PhD, Head of Cell Therapy Technical Development, *Genentech, Inc.*

Panelist: Houman Dehghani, PhD, Vice President, *Cabaletta Bio*

Panelist: Jason Treese, Global Head of Quality, *Galapagos*

Panelist: Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

Panelist: Darius Pillsbury, Senior Consultant, *ValSource, Inc.*

12:55 – 13:25

Guided Poster Walk

Moderator: Josh Eaton, MS, Senior Director, Scientific and Regulatory Affairs, *PDA*

13:05 – 14:10



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Networking Lunch Break, Poster Session & Exhibition

14:10 – 16:35

Session 2: Regulatory Updates

Regulatory Moderator: Marcel Hoefnagel

14:10 – 14:20

Interactive Questionnaire Session

Regulatory Moderator: Marcel Hoefnagel

14:20 – 14:45

Title to be announced

Regulatory Presenter: Andreea Barbu

14:45 – 15:10

Title to be announced

15:10 – 15:35

Regulation on Substances of Human Origin (SoHo): Implications for ATMP Development

Regulatory Presenter: Ander Izeta, PhD, Section Head, *Advanced Therapies Unit/Donostia University Hospital/Basque Health Service*

15:35 – 16:05

Q&A Discussion

Regulatory Moderator: Marcel Hoefnagel

Regulatory Panelist: Andreea Barbu

Regulatory Panelist: Ander Izeta, PhD, Section Head, *Advanced Therapies Unit/Donostia University Hospital/Basque Health Service*

16:05 – 16:35

Networking Coffee Break, Poster Session & Exhibition

16:35 – 18:10

Session 3: Clinical Perspective



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Moderator: Ian Johnston, PhD, Project Lead Translational TCR Drug Development Senior Project Manager - Research & Development , *Miltenyi Biotec B.V. & Co. KG*

18:10 – 18:10

End of Conference Day 1 & Networking Event

Friday, 27 June

08:30 – 09:00

Collaboration or Competition? The Nordic Model in ATMP Innovation

09:00 – 09:05

Welcome Back by the Co-Chairs

Co-Chair: Renske MT ten Ham, PhD, PharmD, MSc, Assistant Professor, *Julius Center, UMC Utrecht*

Co-Chair: Ryan Murray, MS, Senior Consultant, *ValSource, Inc.*

09:05 – 10:30

Session 4: Quality, Safety, and Efficacy

Moderator: Ola Adel, Site Quality Head Aseptics and Cell and Gene Therapy , *Novartis*

10:30 – 11:00

Coffee Break, Poster Session & Exhibition

11:00 – 12:30

Session 5: Manufacturing Challenges

Moderator: Fabio D'Agostino

12:30 – 13:30

Lunch Break, Poster Session & Exhibition

13:30 – 14:35

Closing Plenary Part I



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Moderator: Renske MT ten Ham, PhD, PharmD, MSc, Assistant Professor, *Julius Center, UMC Utrecht*

13:30 – 14:00

Fireside Chat on Centralized vs. Decentralized ATMP Manufacturing

Regulatory Presenter: Roberto Conocchia, MD, GMP Technical Lead, *European Medicine Agency*

Regulatory Presenter: Marcel Hoefnagel

Presenter: Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

14:00 – 14:20

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

Presenter: Orit Gamburg, BPharm MSc MBA, RA & QA Consultant, Project Manager, *GSAP*

14:20 – 14:35

Plenary Discussion

Regulatory Panelist: Roberto Conocchia, MD, GMP Technical Lead, *European Medicine Agency*

Panelist: Orit Gamburg, BPharm MSc MBA, RA & QA Consultant, Project Manager, *GSAP*

Moderator: Renske MT ten Ham, PhD, PharmD, MSc, Assistant Professor, *Julius Center, UMC Utrecht*

14:35 – 15:05

Coffee Break, Poster Session & Exhibition

15:05 – 15:10

Raffle Card Announcement

15:10 – 15:15

Best Poster Presentation

16:20 – 16:30

Co-Chairs Conference Summary

Co-Chair: Renske MT ten Ham, PhD, PharmD, MSc, Assistant Professor, *Julius Center, UMC Utrecht*

Co-Chair: Ryan Murray, MS, Senior Consultant, *ValSource, Inc.*

16:30 – 16:35



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Closing Remarks & Farewell

Committee Member: Falk Klar, PhD, General Manager, Vice President Europe, *Parenteral Drug Association*

16:35 – 16:35

End of Conference