Thursday, 26 June

CEST Daylight Time (UTC +2:00)

08:00 – 18:00	**Registration Hours** Grand Container 1
09:00 – 09:05	**Welcome and Introduction** Grand Container 2-3 **Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*
09:05 – 09:15	**Welcome from the Co-Chairs** Grand Container 2-3 **Co-Chair: Renske MT ten Ham PhD, PharmD, MSc**, Assistant Professor, *Julius Center, UMC Utrecht* **Co-Chair: Ryan Murray MS** Senior Consultant *ValSource, Inc.*
09:15 – 11:15	**Opening Plenary - Past, Present, and Progress: Advancing Cell Therapy Through Innovation and Responsibility** Grand Container 2-3 **Moderator: Ryan Murray MS**, Senior Consultant, *ValSource, Inc.*

09:15 – 09:40	**How the Past Can Advance the Future** Grand Container 2-3 • **Presenter: Stephen Judd CEng, FIChemE FIEI**, European Director of Process Technology, *Arcadis*
09:40 – 10:05	**Future Directions in Cell Therapy Manufacturing and Enablement** Grand Container 2-3 • **Presenter: Tom Bell PhD**, Partner, *L.E.K. Consulting*
10:05 – 10:30	**Reclaim the C's: Feasibility of Recycling Plastic Waste During ATMP Production** Grand Container 2-3 • **Academic Presenter: Nika Gvazava MD**, PhD student , *Lund University*
10:30 – 11:15	**Plenary Discussion** Grand Container 2-3 • **Moderator: Ryan Murray MS**, Senior Consultant, *ValSource, Inc.* • **Panelist: Stephen Judd CEng, FIChemE FIEI**, European Director of Process Technology, *Arcadis*

- **Panelist: Tom Bell PhD**, Partner, *L.E.K. Consulting*
- **Panelist: Nika Gvazava MD**, PhD student , *Lund University*

11:15 – 11:45

Networking Coffee Break, Poster Session & Exhibition

Grand Container 1

Take this opportunity to recharge with a coffee and connect with fellow attendees. Use the time to explore the exhibition area, schedule one-on-one meetings with exhibitors, and expand your network. Don't forget to visit the poster area and engage with the presenters about their exciting research.

11:45 – 12:55

Speed Session 1: Manufacturing

Grand Container 2-3

ATMP manufacturing represents the last leg of a long R&D marathon, which turns raw materials into therapeutic products that treat diseases and save lives. In the ATMP world, true learning usually occurs when manufacturing starts due to process/product complexity and diversity. This session focuses on Quality, Prevention of Cross Contamination, and Aseptic Process & Containment, all critical areas in ATMP manufacturing. In addition, the session will provide an update on the PDA ATMP Advisory Board, outlining the priorities and ongoing activities of the board.

Moderator: Dayue Chen PhD, Distinguished Scientist, *Genentech, Inc.*

11:45 – 11:55

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

Grand Container 2-3

- **Presenter: Houman Dehghani PhD**, Vice President, *Cabaletta Bio*

11:55 – 12:05

Quality Considerations in a Decentralized CAR T Manufacturing Model

Grand Container 2-3

- **Presenter: Jason Treese** , Global Head of Quality, *Galapagos*

12:05 – 12:15

Preventing Cross-Contamination During Manufacturing of ATMPs

Grand Container 2-3

- **Presenter: Richard Denk** , Senior Consultant Aseptic Processing, *SKAN AG*

12:15 – 12:25

PDA ATMP Advisory Board Updates

Grand Container 2-3

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

12:25 – 12:55

Q&A Discussion

Grand Container 2-3

- **Moderator: Dayue Chen PhD**, Distinguished Scientist, *Genentech, Inc.*
- **Panelist: Houman Dehghani PhD**, Vice President, *Cabaletta Bio*
- **Panelist: Jason Treese** , Global Head of Quality, *Galapagos*
- **Panelist: Richard Denk** , Senior Consultant Aseptic Processing, *SKAN AG*
- **Panelist: Darius Pillsbury** , Senior Consultant, *ValSource, Inc.*

Guided Poster Walk

Grand Container 1

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

12:55 – 13:25	**Phenotypic detection via continous metabolic monitoring enables sterility testing in under 3 days with calscreener+** Grand Container 1 • **Poster Presenter: Wilhelm Paulander PhD**, Chief Clinical Development Officer, *Symcel*
12:55 – 13:25	**Flexible aseptic processing under grade A conditions** Grand Container 1 • **Poster Presenter: Adrian Keller** , Strategic Product Management, *SKAN AG*
12:55 – 13:25	**From Breakthrough to Sustainable Success: The Criticality of Contamination Control in ATMP Development** Grand Container 1 • **Poster Presenter: Amanda Curtis** , Microbiology Consultant, *ValSource, Inc.*
12:55 – 13:25	**Establishing State-of-the-Art CAR T Cell Manufacturing Capabilities in a Not-for-Profit Organization in Sweden** Grand Container 1 • **Poster Presenter: Chao Sheng PhD**, Process Development Manager & Team Lead, *CCRM Nordic*
12:55 – 13:25	**Improving safety and quality in ATMP production while enhancing the sustainability of cell factories with closed system.** Grand Container 1 • **Poster Presenter: Pietro Bosi MD**, Business Development Manager, *IWT srl*
12:55 – 13:25	**Navigating the Analytical Landscape: Method Comparison for GMP-Compliant AAV Characterization with TEM** Grand Container 1 • **Poster Presenter: Ashley Stephen Layland** , Project Director, *neotem Bioanalytics-IIT GmbH*
12:55 – 13:25	**Effective Use of Deviron® Detergents for AAV Recovery During Lysis And Viral Inactivation in Gene Therapy Manufacturing** Grand Container 1 • **Poster Presenter: Antoine Heron PhD**, Modality Consultant - Viral Vectors EMEA, *Merck*
12:55 – 13:25	**Developing a Contamination Control Strategy for ATMP Cleanrooms** Grand Container 1 • **Poster Presenter: Renee V. Buthe** , Technical Services Manager, *STERIS Corporation*
12:55 – 13:25	**Maximizing Contamination Control for Classified Areas Through Material Transfer** Grand Container 1 • **Poster Presenter: Renee V. Buthe** , Technical Services Manager, *STERIS Corporation*
	Non-Authorised ATMPs in the Czech Republic: Regulatory Pathways and Patient Access

	12:55 – 13:25	Grand Container 1 • **Poster Presenter: Zora Čechová PharmD, PhD**, Regulatory Specialist, *Centre of Excellence CREATIC, Masaryk University*
	12:55 – 13:25	**Standardisation, automation, decentralisation: a Path for personalised medicine manufacture** Grand Container 1 • **Poster Presenter: Laureline Mahe PhD**, Head of Applied Science, *Team Consulting*
	12:55 – 13:25	**Scalable Stem Cell-Derived Natural Killer Cell Differentiation in an In Vitro Feeder-Free System** Grand Container 1 • **Poster Presenter: Theo Vogiatzoglou** , ,
	12:55 – 13:25	**User-centred design for effective, automated, cGMP bioprocessing platforms in cell & gene therapies** Grand Container 1 • **Poster Presenter: Joseph Conroy MEng**, Consultant Mechanical Engineer, *Team Consulting*
13:05 – 14:10		**Networking Lunch Break, Poster Session & Exhibition** Grand Container 1 This is your time to network and explore! Connect with colleagues, meet new professionals in the field, and take a closer look at the posters. Visit the exhibition booths, book appointments with exhibitors, and complete your Passport Raffle for a chance to win.
14:10 – 16:05		**Session 2: Regulatory Updates** Grand Container 2-3 In this regulatory session we have three great presentations to share some recent developments in the regulations for cell and gene therapy products. The EMA Guideline for Investigational ATMP in Clinical Trials provides support to developers in their CMC development. Andreea Barbu will highlight the elemental parts of that guideline. Development of ATMP is challenging in itself, but this is sometimes further complicated by (perceived) different regulatory expectations in the different regions. Dolca Rogers will inform us about some of the common challenges in development, but also about the efforts on harmonization between EMA and FDA trying to alleviate impact those differences would have for product development. Ander Izeta will discuss the implications for ATMP of the Regulation on Substances of Human Origin (SoHo) will have. The panel discussion will focus on these topics, but undoubtedly, other related topics will come up. **Regulatory Moderator: Marcel Hoefnagel PhD**, Senior Assessor Biopharmaceuticals, *Medicines Evaluation Board*
	14:10 – 14:20	**Interactive Questionnaire Session** Grand Container 2-3 • **Moderator: Ryan Murray MS**, Senior Consultant, *ValSource, Inc.*
	14:20 – 14:45	**Highlights from the EMA Guideline for Investigational ATMP in Clinical Trial** Grand Container 2-3 • **Regulatory Presenter: Andreea Barbu PhD**, Senior assessor, *The Swedish Medical Product Agency*
	14:45 – 15:10	**Common Challenges in the Regulatory Path for ATMPs – International Collaboration for More Harmonized Outcomes** Grand Container 2-3 • **Regulatory Presenter: Dolca Rogers PhD**, Scientific Officer at the Pharmaceutical Quality Office, *European Medicines Agency*

	15:10 – 15:35	**Regulation on Substances of Human Origin (SoHo): Implications for ATMP Development** Grand Container 2-3 • **Regulatory Presenter: Ander Izeta PhD**, Section Head, *Advanced Therapies Unit/Donostia University Hospital/Basque Health Service*
	15:35 – 16:05	**Q&A Discussion** Grand Container 2-3 • **Regulatory Moderator: Marcel Hoefnagel PhD**, Senior Assessor Biopharmaceuticals, *Medicines Evaluation Board* • **Regulatory Panelist: Andreea Barbu PhD**, Senior assessor, *The Swedish Medical Product Agency* • **Regulatory Panelist: Ander Izeta PhD**, Section Head, *Advanced Therapies Unit/Donostia University Hospital/Basque Health Service* • **Regulatory Panelist: Dolca Rogers PhD**, Scientific Officer at the Pharmaceutical Quality Office, *European Medicines Agency*
16:05 – 16:35	**Networking Coffee Break, Poster Session & Exhibition** Grand Container 1 Enjoy a relaxed coffee break while diving into the vibrant atmosphere of our exhibition. Schedule meetings with solution providers, participate in the Passport Raffle, and stop by the PDA photo wall to capture a memory with your new connections.	
16:35 – 18:10	**Session 3: Clinical Perspective** Grand Container 2-3 Would you be willing to consider yourself or a family member as a candidate for treatment with an experimental cell or gene therapy? This session will open with a powerful patient perspective to ground the audience in the ultimate purpose of their daily efforts—advancing and improving the manufacturing of advanced therapy medicinal products (ATMPs). Subsequent presentations will examine the academic development and implementation of cell and gene therapy products, emphasizing how clinical innovation and point-of-care manufacturing are enhancing patient access to these advanced therapeutic modalities. **Moderator: Ian Johnston PhD**, Scientific Director, Project Lead Translational TCR Drug Development Senior Project Manager - Research & Development , *Miltenyi Biotec B.V. & Co. KG*	
	16:35 – 17:00	**A Patient's Journey: Life Before, During, and After Gene Therapy** Grand Container 2-3 • **Presenter: Maria-Luiza Prioteasa** , Parent , *Patient relative*
	17:00 – 17:20	**From Lab to Clinic: Point-of-Care Anti-CD19 CAR-T Cell Therapy Induces Remission in Refractory Acquired Hemophilia A** Grand Container 2-3 • **Academic Presenter: Kalin Stoyanov** , Resident, *Hanover Medical School (MHH)*
	17:20 – 17:40	**Steering Innovation to Clinical Success: The Development of a Fully Personalized Dendritic Cell Vaccine for Pediatric High-Risk Solid Tumors** Grand Container 2-3 • **Academic Presenter: Regina Demlova** , Head of CREATIC CoE, Head of Pharmacology Dept., *Masaryk University, Faculty of Medicine*
		Q&A Discussion

	Grand Container 2-3 17:40 – 18:10 • **Moderator: Ian Johnston PhD**, Scientific Director, Project Lead Translational TCR Drug Development Senior Project Manager - Research & Development , *Miltenyi Biotec B.V. & Co. KG* • **Academic Panelist: Regina Demlova** , Head of CREATIC CoE, Head of Pharmacology Dept., *Masaryk University, Faculty of Medicine* • **Academic Panelist: Kalin Stoyanov** , Resident, *Hanover Medical School (MHH)*
18:10 – 18:10	**End of Conference Day 1 & Networking Event**

Friday, 27 June

CEST Daylight Time (UTC +2:00)

08:00 – 16:30	**Registration Hours** Grand Container 1
08:30 – 09:00	**Collaboration or Competition? The Nordic Model in ATMP Innovation** Grand Container 2-3 This breakfast panel brings together leaders from clinical translation organisations in Denmark, Sweden, and Norway to explore how collaboration and competition shape the Nordic advanced therapy ecosystem. With limited regional resources and growing international pressure, we'll ask where duplication of effort can be reduced, what collaboration models have worked (or failed), and how the Nordics can better coordinate to unlock shared value. Panelists will share how they define success in partnerships, when they choose to collaborate vs. compete, and what they hope Nordic cooperation will look like five years from now. **Moderator: Sarah Callens** , Chief Technology Officer, *CCRM Nordic* **Co-Presenter: Anna Pasetto PhD** Director ACT centre *Oslo University Hospital* **Co-Presenter: Fredrik Wessberg MSc** CEO *CCRM Nordic* **Co-Presenter: Thomas H.R Carlsen PhD** CEO *Novo Nordisk Foundation Cellerator*
09:05 – 10:30	**Session 4: Quality, Safety, and Efficacy** Grand Container 2-3 This session covers product quality, patient safety, and therapeutic efficacy in cell and advanced therapies. Experts will present strategies to enhance manufacturing processes, establish robust control systems, and integrate ethical AI for personalized medicine. Through discussions and case studies, attendees will gain insights into innovative approaches shaping the future of advanced therapies. Mahmoud Asif will begin with insights on particle control strategies for cell therapy manufacturing. Kat Kozyrytska will discuss the application of ethical AI to improve the manufacturability and personalization of ATMPs. Claudia Lee will conclude with case studies on sequencing-based quality control techniques for cell, gene, and mRNA therapies. Expert presentations and discussions will provide attendees with valuable strategies and innovative approaches to advance therapies. **Moderator: Ola Adel** , Site Quality Head Aseptics and Cell and Gene Therapy , *Novartis* 09:05 – 09:25 **Is That a Particle? Establishing a Particle Control Strategy in Cell Therapy** Grand Container 2-3 • **Presenter: Asif Mahmood** , Technical Director - Technology Transfer, *Bristol Myers Squibb* 09:25 – 09:45 **Improving Manufacturability and Personalizing ATMPs with Ethical AI** Grand Container 2-3 • **Presenter: Kat Kozyrytska MS**, Founder, *Cell Therapy Manufacturability Program* **Case Studies of Sequencing Based QC for Cell, Gene and mRNA Therapy**

	09:45 – 10:00	Grand Container 2-3 • **Presenter: Claudia Lee PhD**, VP of R&D, *Velvet Therapeutics*
	10:00 – 10:30	**Q&A Discussion** Grand Container 2-3 • **Moderator: Ola Adel** , Site Quality Head Aseptics and Cell and Gene Therapy , *Novartis* • **Panelist: Asif Mahmood** , Technical Director - Technology Transfer, *Bristol Myers Squibb* • **Panelist: Claudia Lee PhD**, VP of R&D, *Velvet Therapeutics* • **Panelist: Kat Kozyrytska MS**, Founder, *Cell Therapy Manufacturability Program*
10:30 – 11:00	**Networking Coffee Break, Poster Session & Exhibition** Grand Container 1 Grab a coffee, mingle with other participants, and make valuable new contacts. Visit the poster presentations, engage with the authors, and take time to explore the exhibition - your chance to meet key industry players and schedule deeper conversations.	
11:00 – 12:30	**Session 5: Manufacturing Challenges** Grand Container 2-3 Manufacturing cell and gene therapies consistently and at scale remains a complex, evolving challenge but one the industry is steadily learning to navigate. In this session, experts from leading biotech companies and supplier organizations will explore how growing regulatory scrutiny is reshaping raw material strategies, highlight emerging innovations improving AAV yields, and share efforts to bring greater clarity to viral safety expectations in cell therapy. Be part of the conversation driving real progress in the manufacturing of living medicines. **Moderator: Richard Denk** , Senior Consulting Aseptic Processing & Containment, *SKAN AG*	
	11:00 – 11:20	**ATMP Material Classification, Associated Framework for Development of Science & Risk Based Approach** Grand Container 2-3 • **Presenter: Aida Rouzmehr MS**, Material Science Product Lead, *Genentech part of Roche*
	11:20 – 11:40	**AAV Process Intensification: Focus on Upstream Critical Process Parameters** Grand Container 2-3 • **Presenter: Antoine Heron PhD**, Modality Consultant - Viral Vectors EMEA, *Merck*
	11:40 – 12:00	**Ensuring Viral Safety of Cell Therapy Products** Grand Container 2-3 • **Presenter: Manjula Aysola MS**, Senior Regulatory Consultant, *MilliporeSigma*
	12:00 – 12:30	**Q&A Discussion** Grand Container 2-3 • **Moderator: Richard Denk** , Senior Consulting Aseptic Processing & Containment, *SKAN AG* • **Panelist: Aida Rouzmehr MS**, Material Science Product Lead, *Genentech part of Roche* • **Panelist: Antoine Heron PhD**, Modality Consultant - Viral Vectors EMEA, *Merck* • **Panelist: Manjula Aysola MS**, Senior Regulatory Consultant, *MilliporeSigma*
	Networking Lunch Break, Poster Session & Exhibition	

12:30 – 13:30	Grand Container 1 Make the most of your break by combining food and conversation! Stroll through the exhibition, talk to poster presenters about their work, and take part in the Passport Raffle. Stop by the PDA photo wall and create a lasting memory with your peers.
13:30 – 14:35	**Closing Plenary - Turning Challenges Into Change: Charting the Future of ATMPs** Grand Container 2-3 The closing plenary explores key challenges and future directions in ATMP-development. An interactive fireside chat will delve into centralized vs. decentralized manufacturing and the regulatory considerations shaping each model. Followed by a talk addressing the “valley of despair” in drug development—why many ATMPs stall and what’s needed to overcome this gap. Featuring expert perspectives and practical insights, this session aims to reframe barriers as drivers of change and collaboration across the ATMP ecosystem. **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 PhD**, Senior Assessor Biopharmaceuticals, *Medicines Evaluation Board* • **Presenter: Richard Denk** , Senior Consultant Aseptic Processing, *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: **Q&A, Discussion** • **Moderator: Renske MT ten Ham PhD, PharmD, MSc**, Assistant Professor, *Julius Center, UMC Utrecht* • **Regulatory Panelist: Roberto Conocchia MD**, GMP Technical Lead, *European Medicine Agency* • **Panelist: Orit Gamburg BPharm MSc MBA**, RA & QA Consultant, Project Manager, *GSAP*
14:35 – 15:05	**Networking Coffee Break, Poster Session & Exhibition** Grand Container 1 Fuel up with coffee while building your professional network. Use this time to schedule meetings with exhibitors, view the posters and chat with the presenters, and complete your Passport Raffle. And don’t miss the PDA photo wall to snap a fun keepsake!
15:05 – 15:10	**Raffle Card Announcement** Grand Container 2-3
15:10 – 15:15	**Best Poster Presentation** Grand Container 2-3
15:15 – 16:20	**Interactive Round Table Session** Grand Container 2-3 In this dynamic session, we’ll dive into the two hottest topics, as voted by the PDA social media community! The audience will explore: Regulatory strategies for accelerated ATMP approvals & Manufacturing innovation, scalability, and cost reduction. Join the conversation, share your perspective, and collaborate on actionable ideas. Key insights and outcomes will be captured and presented afterward! **Moderator: Renske MT ten Ham PhD, PharmD, MSc**, Assistant Professor, *Julius Center, UMC Utrecht*
	Co-Chairs Conference Summary

16:20 – 16:30	Grand Container 2-3 **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	**Closing Remarks & Farewell** Grand Container 2-3 **Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*
16:35 – 16:35	**End of Conference**