Thursday, 26 June

CEST Daylight Time (UTC +2:00)

08:00 – 18:00	**Registration Hours**
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** **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** **Moderator: Ryan Murray MS**, Senior Consultant, *ValSource, Inc.*

09:15 – 09:40	**How the Past Can Advance the Future** • **Presenter: Stephen Judd CEng, FIChemE FIEI**, European Director of Process Technology, *Arcadis*
09:40 – 10:05	**Future Directions in Cell Therapy Manufacturing and Enablement** • **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** • **Academic Presenter: Nika Gvazava MD**, PhD student , *Lund University*
10:30 – 11:15	**Plenary Discussion** • **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**
	Speed Session 1: Manufacturing **Moderator: Dayue Chen PhD**, Distinguished Scientist, *Genentech, Inc.*

	Demonstrating Analytical Comparability for Complex Manufacturing Process Changes:

11:45 – 12:55	11:45 – 11:55	**Lessons Learned from Technical and Regulatory Perspectives** • **Presenter: Houman Dehghani PhD**, Vice President, *Cabaletta Bio*
	11:55 – 12:05	**Quality Considerations in a Decentralized CAR T Manufacturing Model** • **Presenter: Jason Treese** , Global Head of Quality, *Galapagos*
	12:05 – 12:15	**Preventing Cross-Contamination During Manufacturing of ATMPs** • **Presenter: Richard Denk** , Senior Consultant Aseptic Processing, *SKAN AG*
	12:15 – 12:25	**PDA ATMP Advisory Board Updates** • **Presenter: Darius Pillsbury** , Senior Consultant, *ValSource, Inc.*
	12:25 – 12:55	**Q&A Discussion** • **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

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

12:55 – 13:25	12:55 – 13:25	**Phenotypic detection via continous metabolic monitoring enables sterility testing in under 3 days with calscreener+** • **Poster Presenter: Wilhelm Paulander PhD**, Chief Clinical Development Officer, *Symcel*
	12:55 – 13:25	**Flexible aseptic processing under grade A conditions** • **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** • **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** • **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.** • **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** • **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** • **Poster Presenter: Antoine Heron PhD**, Modality Consultant - Viral Vectors EMEA, *Merck*
	12:55 – 13:25	**Developing a Contamination Control Strategy for ATMP Cleanrooms** • **Poster Presenter: Renee V. Buthe** , Technical Services Manager, *STERIS Corporation*
	12:55 – 13:25	**Maximizing Contamination Control for Classified Areas Through Material Transfer** • **Poster Presenter: Renee V. Buthe** , Technical Services Manager, *STERIS Corporation*
	12:55 – 13:25	**Non-Authorised ATMPs in the Czech Republic: Regulatory Pathways and Patient Access** • **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** • **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** • **Poster Presenter: Theo Vogiatzoglou** , ,
	12:55 – 13:25	**User-centred design for effective, automated, cGMP bioprocessing platforms in cell & gene therapies** • **Poster Presenter: Joseph Conroy MEng**, Consultant Mechanical Engineer, *Team Consulting*
13:05 – 14:10	**Networking Lunch Break, Poster Session & Exhibition**	
14:10 – 16:05	**Session 2: Regulatory Updates** **Regulatory Moderator: Marcel Hoefnagel PhD**, Senior Assessor Biopharmaceuticals, *Medicines Evaluation Board*	
	14:10 – 14:20	**Interactive Questionnaire Session** • **Moderator: Ryan Murray MS**, Senior Consultant, *ValSource, Inc.*
	14:20 – 14:45	**Highlights from the EMA Guideline for Investigational ATMP in Clinical Trial** • **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** • **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** • **Regulatory Presenter: Ander Izeta PhD**, Section Head, *Advanced Therapies Unit/Donostia University Hospital/Basque Health Service*
		Q&A Discussion • **Regulatory Moderator: Marcel Hoefnagel PhD**, Senior Assessor Biopharmaceuticals, *Medicines Evaluation Board*

15:35 – 16:05	• **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**
16:35 – 18:10	**Session 3: Clinical Perspective** **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** • **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** • **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** • **Academic Presenter: Regina Demlova** , Head of CREATIC CoE, Head of Pharmacology Dept., *Masaryk University, Faculty of Medicine*
17:40 – 18:10	**Q&A Discussion** • **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**
08:30 – 09:00	**Collaboration or Competition? The Nordic Model in ATMP Innovation** **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*
	Session 4: Quality, Safety, and Efficacy **Moderator: Ola Adel** , Site Quality Head Aseptics and Cell and Gene Therapy , *Novartis*

09:05 – 10:30	09:05 – 09:25	**Is That a Particle? Establishing a Particle Control Strategy in Cell Therapy** • **Presenter: Asif Mahmood** , Technical Director - Technology Transfer, *Bristol Myers Squibb*
	09:25 – 09:45	**Improving Manufacturability and Personalizing ATMPs with Ethical AI** • **Presenter: Kat Kozyrytska MS**, Founder, *Cell Therapy Manufacturability Program*
	09:45 – 10:00	**Case Studies of Sequencing Based QC for Cell, Gene and mRNA Therapy** • **Presenter: Claudia Lee PhD**, VP of R&D, *Velvet Therapeutics*
	10:00 – 10:30	**Q&A Discussion** • **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**	
11:00 – 12:30	**Session 5: Manufacturing Challenges** **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** • **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** • **Presenter: Antoine Heron PhD**, Modality Consultant - Viral Vectors EMEA, *Merck*
	11:40 – 12:00	**Ensuring Viral Safety of Cell Therapy Products** • **Presenter: Manjula Aysola MS**, Senior Regulatory Consultant, *MilliporeSigma*
	12:00 – 12:30	**Q&A Discussion** • **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*
12:30 – 13:30	**Networking Lunch Break, Poster Session & Exhibition**	
	Closing Plenary - Turning Challenges Into Change: Charting the Future of ATMPs **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,

13:30 – 14:35		*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**	
15:05 – 15:10	**Raffle Card Announcement**	
15:10 – 15:15	**Best Poster Presentation**	
15:15 – 16:20	**Interactive Round Table Session** **Moderator: Renske MT ten Ham PhD, PharmD, MSc**, Assistant Professor, *Julius Center, UMC Utrecht*	
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	**Closing Remarks & Farewell** **Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*	
16:35 – 16:35	**End of Conference**	