



# Agenda

PDA Advanced Therapy Medicinal Products Conference 2024

15:00 – 18:00 | **Registration Open**

Studio 3,4,5,6,7

**Monday, 24 June**

08:00 – 17:30

**Registration Open**

Studio 3,4,5,6,7

09:00 – 09:05

**Welcome and Introduction**

Salon ABC

**Committee Member: Falk Klar, PhD, Parenteral Drug Association**

09:05 – 09:15

**Welcome from the Co-Chairs**

Salon ABC

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

**Co-Chair: Richard Denk, Senior Consulting Aseptic Processing & Containment, SKAN AG**

09:15 – 11:00

**Opening Plenary**

Salon ABC

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

09:15 – 09:40

7 Things I Wish I Knew Before Undergoing Gene Therapy

**Presenter: Jimi Olaghere, Gene Editing Recipient, -**

09:40 – 10:05

EMA's Role in Bringing Gene Therapy Products to Patients

**Regulatory Presenter: Veronika Jekerle, PhD, Head of Pharmaceutical Quality, Human Medicines, European Medicines Agency**

10:05 – 10:30

Enhancing Strategic Decision-Making for ATMP Development & Commercialization: The Role of Supply Chain Business Intelligence

**Presenter: Steffen Schulze, Strategic Analytics & Business Insights Lead, F. Hoffmann-La Roche**



# Agenda

## PDA Advanced Therapy Medicinal Products Conference 2024

10:30 – 11:00

Plenary Discussion

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

**Panelist: Jimi Olaghere**, Gene Editing Recipient, -

**Panelist: Veronika Jekerle, PhD**, Head of Pharmaceutical Quality, Human Medicines, *European Medicines Agency*

**Panelist: Steffen Schulze**, Strategic Analytics & Business Insights Lead, *F. Hoffmann-La Roche*

11:00 – 11:30

Networking Coffee Break, Poster Session & Exhibition

Studio 3,4,5,6,7

11:30 – 13:00

Session 1: Challenges in Manufacturing

Salon ABC

Manufacturability of ATMP represents one of the most difficult challenges in bringing life-saving/changing products to patients. Three presentations in this session will describe this universal challenge from different perspectives ranging from novel modality to lifecycle management. Our speakers will share their stories in dealing with this shared challenge across the ATMP space and yet distinctly different from product to product.

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

11:30 – 11:50

The Challenges of the Innovative Exosome-based Therapies – Case Study

**Presenter: Sandrine Mores, MA, COO**, *ExoXpert*

11:50 – 12:10

"Spilling the Tea" on Leaks in Autologous CAR-T Manufacturing

**Presenter: Rebecca D. Jordan**, Associate Director, Global Cell Therapy Sterility Assurance Lead, *Bristol Myers Squibb (BMS)*

12:10 – 12:30

Visual Inspection & Particle Life Cycle Management in CGT Products - Same, Same but Different?

**Co-Presenter: Roman Mathaes, PhD**, CEO, *Clear Solutions Laboratories*

**Co-Presenter: Antonio Burazer**, Global Head Visual Inspection & Particle LCM, *Takeda Pharmaceuticals International AG*

12:30 – 13:00

Q&A, Discussion



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## PDA Advanced Therapy Medicinal Products Conference 2024

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

**Panelist: Sandrine Mores, MA, COO**, *ExoXpert*

**Panelist: Rebecca D. Jordan**, Associate Director, Global Cell Therapy Sterility Assurance Lead, *Bristol Myers Squibb (BMS)*

**Panelist: Roman Mathaes, PhD**, CEO, *Clear Solutions Laboratories*

**Panelist: Antonio Burazer**, Global Head Visual Inspection & Particle LCM, *Takeda Pharmaceuticals International AG*

13:00 – 14:10

### Networking Lunch Break & Exhibition

Studio 3,4,5,6,7

13:40 – 14:10

### Guided Poster Walk

Studio 3,4,5,6,7

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

13:40 – 14:10

A Novel Approach to Managing Risks in Aseptic Processing of Cell & Gene Therapies

13:40 – 14:10

Biodecontamination of Raw Materials in Packaging Production Process

**Poster Presenter: Andrea Weiss**

13:40 – 14:10

CCS for Material Transfer: Best Practice for Packaging and Surface Disinfection

**Poster Presenter: Bram Van Puymbroeck**, Account Manager, *STERIS Life Sciences*

13:40 – 14:10

Challenges in the Analysis of a Pharmaceutical Lentiviral Vector by Orthogonal Physical (Nano)particle Characterization Techniques

**Poster Presenter: Daniela Stadler, PhD**, Scientist, *Coriolis Pharma Research GmbH*

13:40 – 14:10

Considerations for Cleaning Lipid Nanoparticles (LNPs)<sup>9</sup>

**Poster Presenter: James N. Polarine, MA**, Senior Technical Service Manager, *STERIS Corporation*



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## PDA Advanced Therapy Medicinal Products Conference 2024

13:40 – 14:10

Designing a Disinfectant Program for Advanced Therapy Medicinal Product Manufacturing

**Poster Presenter: James N. Polarine, MA**, Senior Technical Service Manager, *STERIS Corporation*

13:40 – 14:10

Detection of Particulate Matter in Single-Use Systems Applied in the Production of ATMPs

**Poster Presenter: Klaus R. Wormuth, PhD**, Principal Scientist, *Sartorius Stedim Biotech*

13:40 – 14:10

Development of a Dual Reporter Cargo and Systemic Incorporation of a Highly Flexible, Benchtop Automation System to Facilitate rAAV9-Based Novel Capsid Development and Characterization

**Poster Presenter: Chakameh Azimpour, PhD**, Director - Analytical Development, *Capsida Biotherapeutics*

13:40 – 14:10

Harmonizing and Automating the Endotoxin Detection of Cell & Gene Therapy Products with Recombinant Factor C

**Poster Presenter: Christian Faderl**, Project Leader, *bioMérieux*

13:40 – 14:10

Influence of Rubber Stoppers on Immunoglobulin Behavior

**Poster Presenter: Giorgio Fernando De Avelar Francisco, MSc**, R&D project engineer, *Aptar Stelmi SAS*

13:40 – 14:10

Mycoplasma Release Test with Low Volume Protocol: From Sample to Results in Less Than 1 Hour

**Poster Presenter: Caroline Kassim Housseny, PhD**, R&D Biosciences Manager, *bioMérieux*

13:40 – 14:10

Optimization of Electron Microscopical Methods for a Validated Quality Assessment of Adeno-Associated Viruses (AAV)

**Poster Presenter: Ashley Stephen Layland**, Project Director, *neotem Bioanalytics-IIT GmbH*

13:40 – 14:10

Scalable Single-Use Harvest and Clarification Solutions for Cell and Virus Based ATMPs

**Poster Presenter: Marc Noverraz, MSc**, Process Technology Manager - Separation Technologies, *Sartorius*

13:40 – 14:10



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The Myth of the “Non-GMP Space:” The Criticality of Establishing Good Aseptic Practices in the Development Environment

**Poster Presenter: Amanda Curtis**, Microbiology Consultant, *ValSource, Inc.*

13:40 – 14:10

Viral Vectors Inside an Isolator - Approaches to Minimize Their Associated Risks

**Poster Presenter: Maximilian Mittelviehhaus**

13:40 – 14:10

Virus Filtration as an Upstream Risk Mitigation Tool in the Manufacturing of Advanced Therapy Medicinal Products

**Poster Presenter: Michael Lasse, PhD**, Global Product Manager, *Sartorius*

14:10 – 14:20

### Interactive Questionnaire

Salon ABC

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

14:20 – 15:50

### Session 2: From Development to Commercialization

Salon ABC

This session will focus on an exciting new development in European cell and gene therapy where academic centers are advancing new ATMPs into clinical practice and towards national compassionate use implementation or European market authorization following an academic, not-for-profit model. This approach can lead to both the rapid introduction of novel therapies to the market or can improve patient accessibility by generating products functionally like commercial products which may currently have limited availability. The speakers will describe their centralized or point-of-care (decentralized) manufacturing methodologies and present an overview of the clinical data obtained to date. The different approaches employed to gain reimbursement for the cellular drug products with the local authorities will be discussed and the possible regulatory path to drug registration will be debated.

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

14:20 – 14:40

Treatment with Tumor-Infiltrating Lymphocytes (TILs) for Patients with Advanced Melanoma: From a Randomized Phase 3 Trial in Academia towards Marketing Authorization

**Academic Presenter: Inge Jederma, PhD**, Head of Translational Cellular Therapy, *Netherlands Cancer Institute / Antoni van Leeuwenhoek*

14:40 – 15:00

Decentralizing CAR-T Production: Proof of Concept Network Experience with an Academic CAR-T



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## PDA Advanced Therapy Medicinal Products Conference 2024

**Academic Presenter: Eulalia Olesti, PharmD, PhD**, Regulatory Affairs Lead, *Hospital Clinic Barcelona, IDIBAPS*

15:00 – 15:20

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

**Academic Presenter: Jasmijn Korpershoek, MD PhD**, Postdoctoral Researcher, *UMC Utrecht*

15:20 – 15:50

Q&A, Discussion

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

**Panelist: Inge Jederma, PhD**, Head of Translational Cellular Therapy, *Netherlands Cancer Institute / Antoni van Leeuwenhoek*

**Panelist: Eulalia Olesti, PharmD, PhD**, Regulatory Affairs Lead, *Hospital Clinic Barcelona, IDIBAPS*

**Panelist: Jasmijn Korpershoek, MD PhD**, Postdoctoral Researcher, *UMC Utrecht*

15:50 – 16:20

Networking Coffee Break, Poster Session & Exhibition

Studio 3,4,5,6,7

16:20 – 17:50

Session 3: Quality Control

Salon ABC

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

16:20 – 16:40

Addressing the Challenges: Alternative Methods for ATMP Analytics Testing

**Presenter: Sarah E. Sheridan, PhD**, Technical Consultant, *Merck*

16:40 – 17:00

Viral Control Strategy for Allogeneic Cell Therapy

**Presenter: Asena Abay, PhD**, Senior Scientist, *Sanofi*

17:00 – 17:20

Challenges in Developing a Contamination Control Strategy for an ATMP Facility

**Presenter: Arabela X. Cuirolo, PhD**, Sterility Assurance Lead, *Kite Pharma EU B.V.*



# Agenda

PDA Advanced Therapy Medicinal Products Conference 2024

17:20 – 17:50

Q&A, Discussion

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

**Panelist:** Asena Abay, PhD, Senior Scientist, *Sanofi*

**Panelist:** Sarah E. Sheridan, PhD, Technical Consultant, *Merck*

**Panelist:** Arabela X. Cuirolo, PhD, Sterility Assurance Lead, *Kite Pharma EU B.V.*

17:50 – 22:00

End of Conference Day 1 & Networking Event

Tuesday, 25 June

08:00 – 18:00

Registration Open

Studio 3,4,5,6,7

08:30 – 08:35

Welcome to Day 2

Salon ABC

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

**Co-Chair:** Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

08:35 – 10:05

Session 4: Regulatory Updates

Salon ABC

This session will provide an overview and updates on various regulatory expectations for ATMP manufacturing. First, we'll hear about all the 'good practices' needed to manufacture, test, and distribute an ATMP. In addition, there will be updates on 3 draft chapters from the USP covering contamination detection for short shelf-life products using respiration-based, ATP bioluminescence-based, and other rapid microbial methods. Finally, we'll hear from the EDQM providing an update on two general monographs for gene therapy products which have recently been finalized.

**Moderator:** Manjula Aysola, MS, Senior Regulatory Consultant, *MilliporeSigma*

08:35 – 08:55

Navigating Regulatory Challenges: Insights from Developing ATMPs through GMP/GDP/GCP

**Presenter:** Patrick Buschor, Dr., Contracted Qualified Person, *PMS - Process Management System*



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08:55 – 09:15

European Pharmacopoeia - New Approach to Gene Therapy Texts

**Regulatory Presenter: Olga Kolaj-Robin, PhD**, Scientific Programme Manager, *European Directorate for the Quality of Medicines and HealthCare*

09:15 – 09:35

Overview and Future Plans of the USP Rapid Microbiological Methods Subcommittee

**Presenter: Marsha L. Steed**, Founder and CEO / Sr Consultant, *Steed MicroBio / JYA*

09:35 – 10:05

Q&A, Discussion

**Moderator: Manjula Aysola, MS**, Senior Regulatory Consultant, *MilliporeSigma*

**Panelist: Patrick Buschor, Dr.**, Contracted Qualified Person, *PMS - Process Management System*

**Panelist: Marsha L. Steed**, Founder and CEO / Sr Consultant, *Steed MicroBio / JYA*

**Panelist: Olga Kolaj-Robin, PhD**, Scientific Programme Manager, *European Directorate for the Quality of Medicines and HealthCare*

10:05 – 10:35

Networking Coffee Break, Poster Session & Exhibition

Studio 3,4,5,6,7

10:35 – 11:45

Session 5: New Technologies

Salon ABC

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

10:35 – 10:55

Decentralized Manufacturing of Autologous ATMPs: How Technology Innovation Fosters Regulatory Compliance

**Presenter: Ursula Busse, PhD, MBA**, Head of Regulatory Affairs, *Tigen Pharma*

10:55 – 11:15

Frame-by-Frame: How Digital Process Twins Overcome Barriers to Develop Robust ATMP Manufacturing Processes

**Presenter: Sebastian Scheler, Mr.**, Managing Director, *Innerspace GmbH*

11:15 – 11:45





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## PDA Advanced Therapy Medicinal Products Conference 2024

Q&A, Discussion

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

**Panelist: Ursula Busse, PhD, MBA**, Head of Regulatory Affairs, *Tigen Pharma*

**Panelist: Sebastian Scheler, Mr.**, Managing Director, *Innerspace GmbH*

11:45 – 12:45

### Networking Lunch Break, Poster Session & Exhibition

Studio 3,4,5,6,7

12:45 – 12:55

### Interactive Questionnaire

Salon ABC

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

12:55 – 13:35

### Closing Plenary Part I

Salon ABC

The Closing Plenary Session will address the regulatory requirements to produce ATMPs and will also include the presentation of the PDA Points to Consider Documents for Viruses. The focus during this session will be on inspections and when hospital exemptions apply as well as discussions/fireside chat with the Swissmedic about their publication of the Q&A document on Annex 1 as well as requirements for the production of ATMPs. At the Industry Experts Discussion, participants' questions will be answered and the resume discussions during the two conference days.

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

12:55 – 13:10

Points to Consider for the Development, Classification, Manufacture, Control and Testing of Plasmids and Vectors Used in ATMP Production

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

13:10 – 13:35

Inspections of ATMP Production Sites and Hospital Exemption Applications

**Regulatory Presenter: Christianne Reijnders, PhD**, Coordinating/Specialistic Inspector, *Health and Youth Care Inspectorate*

13:35 – 14:05

### Networking Coffee Break, Poster Session & Exhibition

Studio 3,4,5,6,7



# Agenda

## PDA Advanced Therapy Medicinal Products Conference 2024

14:05 – 14:10

### Passport Raffle

Salon ABC

14:10 – 15:45

### Closing Plenary Part II

Salon ABC

The Closing Plenary Session will address the regulatory requirements to produce ATMPs and will also include the presentation of the PDA Points to Consider Documents for Viruses. The focus during this session will be on inspections and when hospital exemptions apply as well as discussions/fireside chat with the Swissmedic about their publication of the Q&A document on Annex 1 as well as requirements for the production of ATMPs. At the Industry Experts Discussion, participants' questions will be answered and the resume discussions during the two conference days.

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

14:10 – 14:35

Fireside Chat: Swissmedic Q&A Document on EU GMP Annex 1 and Requirements for ATMPs

**Regulatory Co-Presenter: Francois Pinsard**, GMDP Inspector ATMP Division, *Swissmedic*

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

14:35 – 15:00

Revision of Guideline ICH Q5A(R2) with Relevance for ATMPs

**Regulatory Presenter: Johannes Bluemel, PhD**, Head of Virus Safety Section, *Paul-Ehrlich-Institut*

15:00 – 15:45

Plenary Discussion

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

**Panelist: Francois Pinsard**, GMDP Inspector ATMP Division, *Swissmedic*

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

**Panelist: Christianne Reijnders, PhD**, Coordinating/Specialistic Inspector, *Health and Youth Care Inspectorate*

**Panelist: Veronika Jekerle, PhD**, Head of Pharmaceutical Quality, Human Medicines, *European Medicines Agency*

**Panelist: Johannes Bluemel, PhD**, Head of Virus Safety Section, *Paul-Ehrlich-Institut*

**Panelist: Olga Kolaj-Robin, PhD**, Scientific Programme Manager, *European Directorate for the Quality of Medicines and HealthCare*

15:45 – 16:00

### Co-Chairs Conference Summary

Salon ABC



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PDA Advanced Therapy Medicinal Products Conference 2024

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

**Co-Chair: Richard Denk**, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

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16:00 – 16:05

Closing Remarks & Farewell

Salon ABC

**Committee Member: Falk Klar, PhD**, *Parenteral Drug Association*