



# Agenda

## PDA Advanced Therapy Medicinal Products Conference 2024

Monday, 24 June

09:00 – 09:05

### Welcome and Introduction

**Committee Member:** Falk Klar, PhD, 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:** Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

09:15 – 11:00

### Opening Plenary

**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

09:40 – 10:05

EMA's Experience in the Development Support and Approval of Gene Therapy Medicinal Products

**Regulatory Presenter:** Veronika Jekerle

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*

10:30 – 11:00

Q&A, Discussion

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

**Panelist:** Jimi Olaghere

**Panelist:** Veronika Jekerle

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





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## PDA Advanced Therapy Medicinal Products Conference 2024

11:00 – 11:30

Networking Coffee Break, Poster Session & Exhibition

11:30 – 13:00

### Session 1: Challenges in Manufacturing

**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**, QC Microbiology Specialist, *Celgene, Biotechnology Company*

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

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

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

**Panelist: Rebecca D Jordan**, QC Microbiology Specialist, *Celgene, Biotechnology Company*

**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

13:40 – 14:10





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## PDA Advanced Therapy Medicinal Products Conference 2024

### Guided Poster Walk

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

14:10 – 14:20

### Interactive Questionnaire

**Moderator: Ian Johnston, PhD**, Academic and Industrial Cooperations ManagerSenior Project Manager - Research & Development, *Miltenyi Biotec B.V. & Co. KG*

14:20 – 15:50

### Session 2: From Development to Commercialization

**Moderator: Ian Johnston, PhD**, Academic and Industrial Cooperations ManagerSenior 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

**Academic Presenter: Eulalia Olesti**

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**, Academic and Industrial Cooperations ManagerSenior 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**

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





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## PDA Advanced Therapy Medicinal Products Conference 2024

15:50 – 16:20

Networking Coffee Break, Poster Session & Exhibition

16:20 – 17:50

### Session 3: Quality Control

**Moderator:** Lori Dingleline, QC Lead- Microbial Control and Compendial Testing, *Spark Therapeutics, 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

17:00 – 17:20

Challenges in Developing a Contamination Control Strategy for an ATMP Manufacturing Site

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

17:20 – 17:50

Q&A, Discussion

**Moderator:** Lori Dingleline, QC Lead- Microbial Control and Compendial Testing, *Spark Therapeutics, Inc.*

**Panelist:** Asena Abay

**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

08:30 – 08:35





# Agenda

## PDA Advanced Therapy Medicinal Products Conference 2024

Welcome to Day 2

**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

**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*

08:55 – 09:15

New Approach of the European Pharmacopoeia to Gene Therapy Products

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

09:15 – 09:35

USP Microbiology Updates on RMM for Short Life Products

**Presenter: Marsha L Steed**, Head of Corporate Microbial Control and Viral Safety, *Resilience*

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**, Head of Corporate Microbial Control and Viral Safety, *Resilience*

**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

10:35 – 11:45

Session 5: New Technologies





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## PDA Advanced Therapy Medicinal Products Conference 2024

**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

How AI Can Transform ATMP Development

**Presenter: Michael N Blackton, MBA**, Founder and CEO, *Blackfin Biopharm Advisors*

11:15 – 11:45

Q&A, Discussion

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

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

**Panelist: Michael N Blackton, MBA**, Founder and CEO, *Blackfin Biopharm Advisors*

11:45 – 12:45

Networking Lunch Break, Poster Session & Exhibition

12:45 – 12:55

Interactive Questionnaire

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

12:55 – 13:35

Closing Plenary Part I

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

12:55 – 13:10

Title to be announced

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

13:10 – 13:35

Inspections of ATMP Production Sites and Hospital Exemption Applications





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## PDA Advanced Therapy Medicinal Products Conference 2024

**Regulatory Presenter:** Christianne Reijnders

13:35 – 14:05

Networking Coffee Break, Poster Session & Exhibition

14:05 – 14:10

Passport Raffle

14:10 – 15:45

Closing Plenary Part II

**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

Title to be announced

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

15:00 – 15:45

Closing Panel 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

**Panelist:** Veronika Jekerle

**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





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## PDA Advanced Therapy Medicinal Products Conference 2024

### Co-Chairs Conference Summary

**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

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