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
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 of 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 of Visual Inspection & Particle LCM, Takeda Pharmaceuticals International AG

13:00 – 14:10
Networking Lunch Break & Exhibition

13:40 – 14:10
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**
15:50 – 16:20
Networking Coffee Break, Poster Session & Exhibition

16:20 – 17:50
Session 3: Quality Control
Moderator: Lori Dingledine, 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: Cheryl E Essex, MSc, Head of Contamination Control, R&D Global Quality, Sanofi

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 Dingledine, QC Lead- Microbial Control and Compendial Testing, Spark Therapeutics, Inc.
Panelist: Cheryl E Essex, MSc, Head of Contamination Control, R&D Global Quality, 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

08:30 – 08:35
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

Co-Presenter: Patrick Buschor

08:55 – 09:15
New Approach of the European Pharmacopoeia to Gene Therapy Products

Regulatory Presenter: Olga Kolaj-Robin

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
Panelist: Marsha L Steed, Head of Corporate Microbial Control and Viral Safety, Resilience
Panelist: Olga Kolaj-Robin

10:05 – 10:35
Networking Coffee Break, Poster Session & Exhibition

10:35 – 11:45
Session 5: New Technologies

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

**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: François 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: François 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*

15:45 – 16:00
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

16:00 – 16:05

Closing Remarks & Farewell

Committee Member: Falk Klar, PhD, Parenteral Drug Association