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

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**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**

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<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>14:20 – 14:40</td>
<td>Treatment with Tumor-Infiltrating Lymphocytes (TILs) for Patients with Advanced Melanoma: From a Randomized Phase 3 Trial in Academia towards Marketing Authorization</td>
<td>Academic Presenter: <strong>Inge Jederma, PhD</strong>, Head of Translational Cellular Therapy, <em>Netherlands Cancer Institute / Antoni van Leeuwenhoek</em></td>
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<td>14:40 – 15:00</td>
<td>Decentralizing CAR-T Production: Proof of Concept Network Experience with an Academic CAR-T</td>
<td>Academic Presenter: <strong>Eulalia Olesti</strong></td>
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<td>15:00 – 15:20</td>
<td>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</td>
<td>Academic Presenter: <strong>Jasmijn Korpershoek, MD PhD</strong>, Postdoctoral Researcher, <em>UMC Utrecht</em></td>
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<td>15:20 – 15:50</td>
<td>Q&amp;A, Discussion</td>
<td><strong>Moderator: Ian Johnston, PhD, Academic and Industrial Cooperations ManagerSenior Project Manager - Research &amp; Development, Miltenyi Biotec B.V. &amp; Co. KG</strong></td>
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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.*

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<th>Time</th>
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<td>16:20 – 16:40</td>
<td>Addressing the Challenges: Alternative Methods for ATMP Analytics Testing</td>
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<td><strong>Presenter:</strong> Sarah E. Sheridan, PhD, Technical Consultant, <em>Merck</em></td>
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<td>16:40 – 17:00</td>
<td>Viral Control Strategy for Allogeneic Cell Therapy</td>
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<td><strong>Presenter:</strong> Cheryl E Essex, MSc, Head of Contamination Control, R&amp;D Global Quality, <em>Sanofi</em></td>
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<td>17:00 – 17:20</td>
<td>Challenges in Developing a Contamination Control Strategy for an ATMP Manufacturing Site</td>
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<td><strong>Presenter:</strong> Arabela X. Cuirolo, PhD, Sterility Assurance Lead, <em>Kite Pharma EU B.V.</em></td>
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<td>17:20 – 17:50</td>
<td>Q&amp;A, Discussion</td>
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<td><strong>Panelist:</strong> Asena Abay</td>
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<td><strong>Panelist:</strong> Sarah E. Sheridan, PhD, Technical Consultant, <em>Merck</em></td>
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17:50 – 22:00

End of Conference Day 1 & Networking Event
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

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<td>08:35</td>
<td>Navigating Regulatory Challenges: Insights from Developing ATMPs through GMP/GDP/GCP</td>
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<td>Presenter: Patrick Buschor</td>
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<td>08:55</td>
<td>New Approach of the European Pharmacopoeia to Gene Therapy Products</td>
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<td>Regulatory Presenter: Olga Kolaj-Robin</td>
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<td>09:15</td>
<td>USP Microbiology Updates on RMM for Short Life Products</td>
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<td>Presenter: Marsha L Steed, Head of Corporate Microbial Control and Viral Safety, Resilience</td>
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<td>10:05</td>
<td>Q&amp;A, Discussion</td>
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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.
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<td>10:35 – 10:55</td>
<td>Decentralized Manufacturing of Autologous ATMPs: How Technology Innovation Fosters Regulatory Compliance</td>
<td><strong>Presenter:</strong> Ursula Busse, PhD, MBA, Head of Regulatory Affairs, <em>Tigen Pharma</em></td>
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<td>10:55 – 11:15</td>
<td>How AI Can Transform ATMP Development</td>
<td><strong>Presenter:</strong> Michael N Blackton, MBA, Founder and CEO, <em>Blackfin Biopharm Advisors</em></td>
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| 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:** 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

15:45 – 16:00
Co-Chairs Conference Summary
16:00 – 16:05

Closing Remarks & Farewell

Committee Member: Falk Klar, PhD, Parenteral Drug Association