# PDA Advanced Therapy Medicinal Products Conference 2026

## Agenda

## Thursday, 25 June

CEST Daylight Time (UTC +2:00)

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| 09:00 – 09:10 | **Welcome and Introduction**<br>**Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association* |
| 09:10 – 09:20 | **Welcome from the Co-Chairs**<br>**Co-Chair: Ryan Murray MS**, Senior Consultant, *ValSource, Inc.*<br>**Co-Chair: Rebecca D. Jordan** Director, Global Cell Therapy Sterility Assurance Lead *Bristol Myers Squibb* |
| 09:20 – 11:15 | **Opening Session: Regulatory Horizons in The Age of Intelligence**<br>**Moderator: Ryan Murray MS**, Senior Consultant, *ValSource, Inc.* |

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| 09:20 – 09:45 | **Japan's Standards for Raw Materials Used in ATMPs**<br>• **Regulatory Presenter: Yoji Sato** , , |
| 09:45 – 10:10 | **Title to be announced** |
| 10:10 – 10:35 | **Manufacturing ATMPs in the EU: Regulatory Perspectives and Challenges**<br>• **Regulatory Presenter: Roberto Conocchia MD**, GMP Technical Lead, *European Medicine Agency* |
| 10:35 – 11:15 | **Q&A and Discussion**<br>• **Moderator: Ryan Murray MS**, Senior Consultant, *ValSource, Inc.*<br>• **Panelist: Yoji Sato** , ,<br>• **Panelist: Roberto Conocchia MD**, GMP Technical Lead, *European Medicine Agency* |

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| 11:15 – 11:45 | **Networking Coffee Break, Poster Session & Exhibition** |
| | **Session 1: Automation, Robotics & Digital Transformation in Cell and Gene Therapy Manufacturing**<br>Automation with robotics and digital transformation are key enablers in the next decade for high manufacturing output, cost reduction, and product safety. Alongside these advantages, there are also challenges that must be addressed. How can we achieve a high degree of automation, modular decentralized manufacturing, and GMP compliance, data integrity, and traceability in complex and flexible manufacturing processes?<br>**Moderator: Richard Denk** , Senior Consultant Aseptic Processing, *SKAN AG* |

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| 11:45 – 12:05 | **Modular and Robotic Process for Cell Therapy Manufacturing**<br>• **Co-Presenter: Fabio Dondi MSc Mechanical Engineering**, R&D Manager, *Fedegari*<br>• **Co-Presenter: Alice Melocchi PhD**, Associate Professor; Chief Scientific Officer, *Università degli Studi di Milano; Multiply Labs, Inc.* |

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| 11:45 – 13:15 | 12:05 – 12:25 | **Pipettes, Pixels, and Pipelines – Making Cell Therapy Automation Approachable**<br>• **Presenter: Anne Baldwin** , Principle Automation Engineer, *Genentech* |
| | 12:25 – 12:45 | **Title to be announced**<br>• **Academic Presenter: Ines Groß-Weege MSc**, Research Fellow, *Fraunhofer Institute for Production Technology* |
| | 12:45 – 13:15 | **Q&A and Discussion**<br>• **Moderator: Richard Denk** , Senior Consultant Aseptic Processing, *SKAN AG*<br>• **Panelist: Riccardo Masili** , ,<br>• **Panelist: Alice Melocchi PhD**, Associate Professor; Chief Scientific Officer, *Università degli Studi di Milano; Multiply Labs, Inc.*<br>• **Panelist: Anne Baldwin** , Principle Automation Engineer, *Genentech*<br>• **Panelist: Ines Groß-Weege MSc**, Research Fellow, *Fraunhofer Institute for Production Technology* |
| 13:15 – 13:45 | **LIVE Guided Poster Walk**<br>**Moderator: Josh Eaton MS**, Senior Director, Scientific and Regulatory Affairs, *PDA* | |
| 13:30 – 14:45 | **Networking Lunch Break, Poster Session & Exhibition** | |
| 14:45 – 16:15 | **Session 2**<br>**Moderator: Claudia Lee PhD**, VP of R&D, *Velvet Therapeutics* | |
| | 14:45 – 15:05 | **Development and Validation of a Dual-Purpose NGS Platform for rAAV Identity and Variant Detection Testing**<br>• **Presenter: Megan Gura PhD**, Principal QC Virology Scientist, *Regeneron Pharmaceuticals, Inc.* |
| | 15:05 – 15:25 | **Advancements in QC Microbiology Automation & Digitalization**<br>• **Presenter: George Bouras MSc, MBA**, Commercial Application Manager Automation & Robotics - EMEA, *Merck* |
| | 15:25 – 15:45 | **Navigating Practical Challenges in Replication-Competent Lentivirus (RCL) Testing to Ensure Regulatory Compliance**<br>• **Presenter: Anna Woodward PhD**, Technical Consultant, *Merck* |
| | 15:45 – 16:15 | **Q&A and Discussion**<br>• **Moderator: Claudia Lee PhD**, VP of R&D, *Velvet Therapeutics*<br>• **Panelist: Megan Gura PhD**, Principal QC Virology Scientist, *Regeneron Pharmaceuticals, Inc.*<br>• **Panelist: George Bouras MSc, MBA**, Commercial Application Manager Automation & Robotics - EMEA, *Merck*<br>• **Panelist: Anna Woodward PhD**, Technical Consultant, *Merck* |
| 16:15 – 16:45 | **Networking Coffee Break, Poster Session & Exhibition** | |
| | **Session 3: Operational Excellence for ATMPs: Optimizing Shop Floor Execution** | |

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| 16:45 – 17:50 | | **Moderator: Ola Adel MA**, Site Quality Head Aseptics and Cell and Gene Therapy , *Novartis* |
| | 16:45 – 17:00 | **Advancing rAAV Manufacturing: Leveraging Platform Processes & Agile Development Tools**<br>• **Presenter: Hannah Seo PhD**, Principal Scientist, *Bristol Myers Squibb* |
| | 17:00 – 17:20 | **Operationalizing Lab-in-the-Loop for iPSC Cell Therapy Development**<br>• **Presenter: Ro DeJesus MPH**, Senior Scientific Manager, *Genentech* |
| | 17:20 – 17:50 | **Q&A and Discussion**<br>• **Moderator: Ola Adel MA**, Site Quality Head Aseptics and Cell and Gene Therapy , *Novartis*<br>• **Panelist: Hannah Seo PhD**, Principal Scientist, *Bristol Myers Squibb*<br>• **Panelist: Ro DeJesus MPH**, Senior Scientific Manager, *Genentech* |
| 17:50 – 17:50 | | **End of Conference Day 1 & Networking Event** |

# Friday, 26 June

CEST Daylight Time (UTC +2:00)

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| 09:00 – 09:05 | | **Welcome Back by the Co-Chairs**<br>**Co-Chair: Rebecca D. Jordan** , Director, Global Cell Therapy Sterility Assurance Lead, *Bristol Myers Squibb*<br>**Co-Chair: Ryan Murray MS** Senior Consultant *ValSource, Inc.* |
| 09:05 – 10:25 | | **Session 4: Contamination Strategies in ATMP Manufacturing**<br>Most ATMP processes today are executed in a combination of closed and open manufacturing steps. With drug products that are often characterized by short shelf lives, limited sterilization possibilities and frequent transfer steps, an optimized clean room strategy adapted to the specific requirements of the process is highly critical to minimizing the manufacturing costs. In this session, experts from different backgrounds share insights into how to organize clean rooms and contamination control strategies.<br>**Moderator: Judith Koliwer PhD**, Senior Industry Advisor & Principal Consultant Advanced Therapies, *Körber Pharma Software* |
| | 09:05 – 09:25 | **A Novel Risk-Based Strategy to Enhance Airflow Visualization Studies (AVS)**<br>• **Co-Presenter: Tiffany A. Baker MBA**, Senior Consultant, *ValSource, Inc.*<br>• **Co-Presenter: James Wamsley** , Consultant, *ValSource, Inc.* |
| | 09:25 – 09:35 | **Title to be announced**<br>• **Presenter: Claudia Lee PhD**, VP of R&D, *Velvet Therapeutics* |
| | 09:35 – 09:55 | **Barrier Technologies and Contamination Control Strategies for ATMP Manufacturing under GMP**<br>• **Co-Presenter: Birte Scharf PhD**, Senior Scientist GMP Compliance, *Franz Ziel GmbH*<br>• **Co-Presenter: James Lindsay Drinkwater** , Head of GMP compliance, *Franz Ziel GmbH* |
| | | **Q&A and Discussion**<br>• **Moderator: Judith Koliwer PhD**, Senior Industry Advisor & Principal Consultant Advanced Therapies, *Körber Pharma Software* |

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| | 09:55 – 10:25 | • **Panelist: Tiffany A. Baker MBA**, Senior Consultant, *ValSource, Inc.*<br>• **Panelist: James Wamsley** , Consultant, *ValSource, Inc.*<br>• **Panelist: Claudia Lee PhD**, VP of R&D, *Velvet Therapeutics*<br>• **Panelist: Birte Scharf PhD**, Senior Scientist GMP Compliance, *Franz Ziel GmbH* |
| 10:25 – 10:55 | **Networking Coffee Break, Poster Session & Exhibition** | |
| 10:55 – 12:25 | **Session 5: Lifecycle Risk Management**<br>As the ATMP landscape shifts toward the "Age of Intelligence," the complexity of maintaining product quality across borders has never been higher. This session explores the critical intersections of digital innovation, supply chain integrity, and material compliance. Attendees will gain practical insights into managing lifecycle risks—from the early-stage selection of GMP raw materials to the high-stakes management of global temperature excursions and the regulatory hurdles of integrated digital delivery systems.<br>**Moderator: Lori Dingledine** , QC Lead- Microbial Control and Compendial Testing, *Spark Therapeutics, Inc.* | |
| | 10:55 – 11:15 | **Hybrid ATMP and Digital Delivery Systems: Regulatory Challenges and Global Considerations**<br>• **Academic Presenter: Afrah Mujeeb AM**, Regulatory Affairs Specialist, *FDA Blueprint* |
| | 11:15 – 11:35 | **From Guideline to Practice: Temperature Excursion Management**<br>• **Presenter: Milena Opacic PhD**, Principal Scientist II, *Johnson&Johnson* |
| | 11:35 – 11:55 | **Timing for Implementation of GMP Raw Materials for ATMPs**<br>• **Presenter: Rachael Atlee** , VP Opertations, *Akron Bio* |
| | 11:55 – 12:25 | **Q&A and Discussion**<br>• **Moderator: Lori Dingledine** , QC Lead- Microbial Control and Compendial Testing, *Spark Therapeutics, Inc.*<br>• **Panelist: Afrah Mujeeb AM**, Regulatory Affairs Specialist, *FDA Blueprint*<br>• **Panelist: Milena Opacic PhD**, Principal Scientist II, *Johnson&Johnson*<br>• **Panelist: Rachael Atlee** , VP Opertations, *Akron Bio* |
| 12:25 – 13:25 | **Networking Lunch Break, Poster Session & Exhibition** | |
| 13:25 – 14:25 | **Interactive Session**<br>**Moderator: Francesco Cicirello PharmD, MSc**, Senior Director Global BioNTainer Quality Compliance, *BioNTech US* | |
| 14:25 – 14:55 | **Networking Coffee Break, Poster Session & Exhibition** | |
| 14:55 – 15:00 | **Passport Raffle**<br>**Moderator: Melanie Decker** , , *Parenteral Drug Association* | |
| 15:00 – 15:05 | **Best Poster Presentation** | |
| | **Closing Session**<br>**Moderator: Rebecca D. Jordan** , Director, Global Cell Therapy Sterility Assurance Lead, *Bristol Myers Squibb* | |
| | 15:05 – 15:25 | **Fireside Chat**<br>• **Regulatory Presenter: Christina Meissner PhD**, Group Manager, *AGES - Austrian Agency for Health and Food Safety GmbH* |

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| | | • **Co-Presenter: Richard Denk** , Senior Consultant Aseptic Processing, *SKAN AG* |
| 15:05 – 16:15 | 15:25 – 15:45 | **Title to be Announced**<br>• **Regulatory Presenter: Ilona Reischl-Kok PhD**, Assessor, *Austrian Medicines and Medical Devices Agency (AGES MEA)* |
| | 15:45 – 16:15 | **Q&A, Discussion**<br>• **Moderator: Rebecca D. Jordan** , Director, Global Cell Therapy Sterility Assurance Lead, *Bristol Myers Squibb*<br>• **Panelist: Christina Meissner PhD**, Group Manager, *AGES - Austrian Agency for Health and Food Safety GmbH*<br>• **Panelist: Ilona Reischl-Kok PhD**, Assessor, *Austrian Medicines and Medical Devices Agency (AGES MEA)* |
| 16:15 – 16:25 | | **Co-Chairs Conference Summary**<br>**Co-Chair: Rebecca D. Jordan** , Director, Global Cell Therapy Sterility Assurance Lead, *Bristol Myers Squibb*<br>**Co-Chair: Ryan Murray MS** Senior Consultant *ValSource, Inc.* |
| 16:25 – 16:30 | | **Closing Remarks & Farewell**<br>**Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association* |
| 16:30 – 16:30 | | **End of Conference** |