ADVANCED THERAPY MEDICINAL PRODUCTS CONFERENCE

NEXT STEPS IN ATMPS AND BEYOND
pda.org/EU/2024ATMP

24-25 JUNE 2024
AMSTERDAM, THE NETHERLANDS
EXHIBITION: 24-25 JUNE 2024

CALL FOR ABSTRACTS

ABSTRACT SUBMISSION DEADLINE:
26 JANUARY 2024
Dear Colleague,

We would like to invite you to submit an abstract for a podium or poster presentation at the 2024 PDA Advanced Therapy Medicinal Products Conference to take place on 24-25 June 2024 in Amsterdam, The Netherlands.

Abstracts and posters must be non-commercial, describing new developments or work that significantly contributes to the knowledge related to Advanced Therapy Medicinal Products.

The Scientific Program Planning Committee will review all proposals carefully and consider podium and poster contributions.

We look forward to receiving your topic proposal!

Sincerely,
The Co-Chairs

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**TOPICS AREAS OF INTEREST WILL INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING**

### 1. CELL AND GENE PRODUCTS
- Stem Cell Transplantation
- Induced Pluripotent Stem Cells: Opportunities and Risks
- Gene Editing
- Prime Editing
- CRISPR
- CAR T-Cells
- Short Hairpin RNA Technology
- Plasmids
- Transposons
- Exosomes

### 2. REGENERATIVE MEDICAL PRODUCTS
- Scaffolds
- Autologous, Allogeneic, or Xenogeneic Pathways
- Mastering the Inflammatory Effect
- Inhibiting Cell Apoptosis
- Differentiating Tissues into Expected Cells/Tissue

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### 3. REGULATORY UPDATES
- EU Guideline on GMP for ATMPs
- PIC/S Revision of GMP Guide Annex 2A (Manufacturing of Advanced Therapy Medicinal Products)
- PIC/S Revision of GMP Guide Annex 2B (Biological Medicinal Substances and Products for Human Use)
- Correlation Between EU Guideline on GMP for ATMPs and Annex 1: 2022
- Harmonization Efforts in GMO Regulation
- Regulatory Requirements for Process Validation
- ICH QSA
- Comparability Guidance

### 4. RAW MATERIALS AND EQUIPMENT
- Cells, Sera, Buffers
- Characterization of Starting Materials and Cell Lines
- Securing Raw Material Supply Throughout Full Life Cycle
- Equipment for Cell Harvest
- Application Systems/Delivery Devices
- Digitalization of Manufacturing/Testing Equipment

### 5. MANUFACTURING OF ATMPs
- Manufacturing Process and Unit Operations
- CMC Aspects
- Facility Design for Shared Manufacturing
- Challenges with Multi-Product Manufacturing Environment
- Non-Viral Modification (Transfection, Transduction)
- mRNA Platform
- Platform Technologies
- Closed Systems vs Open Systems
- Final Formulation Design
- Visual Inspection
- Organs/Cell Factories on a Chip
- Viral Vector Production
- Aseptic Processing
- Process Control Strategy
- Contamination Control Strategy
- Sterility Assurance
- Validation Strategies
- Automation and Robotics
- Virus Safety
- Decentralized Manufacturing
- GMP, Environment, and Occupational Safety
- Cost of Goods
TOPICS ARE OF SPECIAL INTEREST WILL INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING

6. ANALYTICAL DEVELOPMENT AND TESTING
- Development and Qualification of Bioassays
- Challenges in Specification Setting (e.g., Potency, Comparability)
- Contamination-Related Quality Tests (e.g., Mycoplasma, Bacteria, Fungi)
- Next Generation Sequencing
- Validation of Analytical Methods
- Viral Safety Aspects
- Challenges in Demonstrating Product Comparability Throughout Development
- Cost and Speed of Quality Control Testing
- Conditional Release
- Automation of Testing

7. STORAGE, TRANSPORT, AND DISTRIBUTION
- Labeling
- Track and Trace Concepts
- Primary Containers and Closure Systems
- Cryo Storage
- Freezing/Thawing Equipment
- Bio-Preservation
- Cold Chain Logistics
- Shipping Validation
- Hold Studies
- Logistical Challenges and Solutions

8. CLINICAL ASPECTS
- Clinical Development
- Design of Clinical Trials and Role of Pivotal Studies
- Immuno-Profiling
- Novel Therapies for Various Cancers
- Measuring Treatment Response
- Correlation of Data on Manufacturing and Outcome
- Importance of Potency Assays for Clinical Outcome
- Administration Devices
- Point of Care Standards for Drug Administration
- Companion Diagnostics
- Standardization of Apheresis

9. FROM LAB TO MARKET
- Similarities and Differences of Pre-Clinical, Clinical, and Commercial Products
- Yield and Scalability Strategies
- Intellectual Property Considerations
- Technology Transfer
- Contract Manufacturing
- Market Requirements and Framework for Commercialization of ATMPs
- Innovative Payment Models
- Challenges in Financing, Pricing, and Reimbursement
- Combining One-Time Treatment with Value of Life-Long Benefit
- Payment upon Treatment Success
- Models of Collaboration Between Hospitals, Small or Medium-Sized Companies, and Big Pharma Companies
- Risk-Based Strategies in Qualification

10. SUSTAINABILITY
- Ecological Footprint
- Energy Consumption Reduction
- Environmental Protection
- Carbon Footprint
- Biosafety During and After Manufacturing
- Adeno-Associated Viral Vector Containment
- Waste Management

CASE STUDIES AND CURRENT CHALLENGES ARE OF SPECIAL INTEREST.
SUBMISSION PROCESS

DEADLINE:
26 JANUARY 2024

All submitted abstracts will be reviewed by the Scientific Program Planning Committee for acceptance. PDA Europe will provide a complimentary registration per on-site podium presentation.

Additional on-site presenters are required to pay the conference registration fee.

Abstracts not selected for a podium presentation may be invited to join as a scientific poster contribution. On-site poster presenters are required to pay the conference registration fee and an additional printing fee will apply.

THE ONLINE PROCESS ASKS YOU TO PROVIDE THE FOLLOWING INFORMATION:
- PRESENTATION TITLE
- PRESENTER’S NAME AND CONTACT DETAILS
- PRESENTER’S BIOGRAPHY (APPROX. 100 WORDS)
- ADDITIONAL SPEAKERS (IF APPLICABLE)
- KEY OBJECTIVES OF TOPIC
- 2-3 PARAGRAPH ABSTRACT, SUMMARIZING THE TOPIC (MAX 300 WORDS)

Please click or scan the QR Code to submit your abstract.

If you have any further questions, please do not hesitate to contact programs-europe@pda.org

TO EXHIBIT: PDA is seeking vendors who provide products/services in support of this conference. Space on-site is limited and is on a first-come, first-serve basis. To reserve your space, please contact Christopher Haertig at expo-europe@pda.org.
To join our scientific poster session, the poster has to be non-commercial in nature. Please send a printable PDF file according to the following specifications:

**Canvas Size to Work on:**
85 cm x 120 cm (33.465 x 47.244 in)  
Portrait Format  
Slug / Bleed: 2 mm (0.079 in)

**Images:**
120dpi (low) - 150dpi (high)  
Depending on size  
All Images Color Profile  
ISO Coated v2 (ECI)

**Document size of the PDF:**
85 cm x 206 cm  
(33.465 x 81.102 in)  
Portrait Format  
Slug / Bleed: 2 mm (0.079 in)

**ALL POSTERS WILL BE PRINTED BY PDA AND DISPLAYED AS PART OF THE EXHIBITION.**
Please send your file and poster title to Christopher Haertig expo-europe@pda.org

**JOIN OUR GUIDED POSTER WALK IN OUR EXHIBITION HALL AND GAIN MORE VISIBILITY**

YOU WILL HAVE THE CHANCE TO ENGAGE WITH OUR POSTER AUDIENCE!
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<td>2024 PDA Visual Inspection Forum</td>
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