2024 PDA

ADVANCED THERAPY MEDICINAL PRODUCTS CONFERENCE

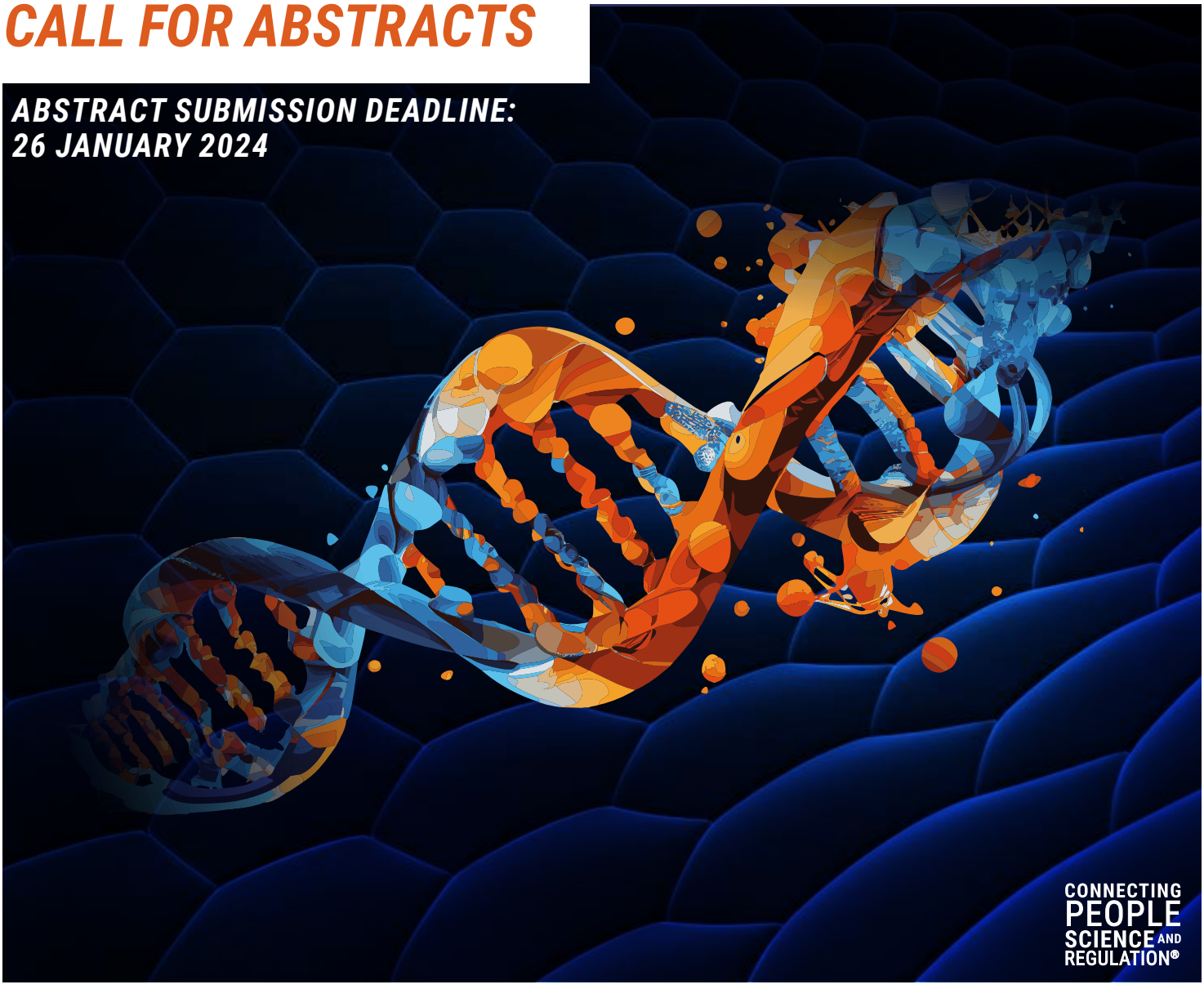
NEXT STEPS IN ATMPS AND BEYOND

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



WELCOME FROM THE CO-CHAIRS

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

Renske ten Ham,
Uni Medical Center Utrecht

Richard Denk,
SKAN

CALL FOR ABSTRACTS

TOPICS AREAS OF INTEREST WILL INCLUDE BUT

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

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 Q5A
- 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

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Renske ten Ham, *University Medical Center Utrecht*
Richard Denk, *SKAN*
Manjula Aysola, *Merck*
Manuel Carrondo, *ibet*
Dayue Chen, *Genentech/Roche*
Fabio D'Agostino, *Charabio*
Lori Dingledine, *Spark Therapeutics*
Irving Ford, *Bristol-Myers Squibb*
Markus Haindl, *Roche*
Marcel Hoefnagel, *MEB*
Ian Johnston, *Miltenyi*
Ryan Murray, *ValSource*
Josh Eaton, *PDA*
Falk Klar, *PDA Europe*
Caroline Lynar, *Manager Programs & Events, PDA Europe*

VENUE

AMSTERDAM MARRIOTT HOTEL
Stadhouderskade 12, 1054 ES Amsterdam, The Netherlands
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E-Mail: Amsterdam@Marriott.com | https://bit.ly/461euWo

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

10. SUSTAINABILITY

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

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

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.

https://bit.ly/3R2eRtp

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.**

DEADLINE: 10 MAY 2024

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!

PDA EUROPE

CONFERENCES AND EVENTS

FOR FURTHER INFORMATION
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2024

3. December 2023

09-10 APR 2024	2024 PDA Visual Inspection Forum	Munich, Germany
23-24 APR 2024	2024 PDA Parenteral Packaging Conference	Copenhagen, Denmark
15-16 MAY 2024	2024 PDA Good Aseptic Manufacturing Conference	Stuttgart, Germany
04-05 JUN 2024	2024 PDA Good Digitalization in Pharma Conference	Antwerp, Belgium
04-05 JUN 2024	2024 PDA Medical Devices and Connected Health Conference	Antwerp, Belgium
06 JUN 2024	2024 PDA Artificial Intelligence in Pharma Workshop	Antwerp, Belgium
06 JUN 2024	2024 PDA The Future of Drug Delivery Workshop	Antwerp, Belgium
24-25 JUN 2024	2024 PDA Advanced Therapy Medicinal Products Conference	Amsterdam, The Netherlands
26-27 JUN 2024	2024 PDA Virus Conference	Amsterdam, The Netherlands
28 JUN 2024	2024 PDA Next-Generation Sequencing Workshop	Amsterdam, The Netherlands
24-25 SEP 2024	2024 PDA BioManufacturing Conference	Gothenburg, Sweden
26 SEP 2024	2024 PDA Sustainability in Pharma Workshop	Gothenburg, Sweden
05-06 NOV 2024	2024 PDA Annex 1 Workshop	Dublin, Ireland