

AGENDA Friday, June 14th, 8:00 a.m.-5:15 p.m.

8:00-8:45 a.m. Check in

Plenary Session

Grand Ballroom

8:45-9:00 a.m. **Opening Remarks:** **Yufeng Li**, Ph.D., President SAPA-GP 2024-25; Conference Co-Chair; Director, Clinical Scientist, Vivace

9:00-9:45 a.m. **Keynote speech: Advancing the Development of Novel Biologic Products**

Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research, FDA

9:45-10:05 a.m. **Coffee Break and Networking**

10:05-11:35 a.m. Parallel Sessions

Gene Therapy

Grand Ballroom

Session 1: Navigating the Challenges in Gene Therapy

Session chair: **Lili Wang**, Ph.D., Research Associate Professor Emeritus, Gene Therapy Program, University of Pennsylvania

10:05-10:35 a.m. **Immunogenicity to AAV Gene Therapy - Challenges and Advancements**

Renuka Pillutla, Ph.D., SVP, Head of Development Sciences, Spark Therapeutics

10:35-11:05 a.m. **Integrated AAV Vector Genomes and the Future of Liver Gene Therapy**

Jenny Greig, Ph.D., Executive Director of Gene Therapy Program, University of Pennsylvania

11:05-11:35 a.m. **Regulatory Considerations for Gene Therapy Development**

Sonali Patel, Pharm.D., Director of Regulatory Affairs, Spark Therapeutics

Chemistry, Manufacturing and Controls (CMC)

Centennial 1

Session 1: Standing on the Shoulder of Giants: Current CMC Strategy and Future Development Trends

Session chair: **Huize Yan**, M.S., Process Development Scientist, Spark Therapeutics

10:05-10:10 a.m. **Track Lead Opening**

10:10-10:40 a.m. **Leveraging the Power of an iPSC Platform to Produce NK and T Cells at Low Cost and High Volume**

Gregory Russotti, Ph.D., CTO & CMO, Century Therapeutics

10:40-11:10 a.m. **Navigating the Challenges in Gene Therapy: Gene Therapy Overview, Challenges, and Future Prospective**
Kenneth Gene Yancey, Ph.D., Executive Director, Process Development & Manufacturing, Gene Therapy Program, University of Pennsylvania

11:10-11:35 a.m. **Panel Discussion**

Morning speakers

Business Track-1

Centennial 2

Session 1: Maximizing Economic Incentives in Greater Philadelphia to Grow Biotech Startups

Session chair: **Bryan Tsao**, Ph.D., Manager, Life Science & Healthcare Initiatives, Chamber of Commerce for Greater Philadelphia

10:05-11:35 a.m. **Panel Discussion and Q&A**

Panelists:

- **Melina Blees**, Ph.D., Site Head, BioLabs Philadelphia
- **Rebecca Grant**, DVM, Sr. Director, Life Sciences & Biotechnology Philadelphia Department of Commerce
- **Ian McLaughlin**, Ph.D., VP of Government Affairs, BioNJ
- **Noah Olson**, M.B.A., Director of Innovation, Delaware Prosperity Partnership

Business Track-2

Centennial 3

Session 1: Intellectual Property Protection and Licensing Strategies for Cell and Gene Therapy Companies

Session chair: **Steve Jannetta**, Partners, Morgan Lewis, Philadelphia Office

Panelists:

- **Lou Beardell**, Partner, Morgan Lewis. Philadelphia Office
- **Laurie Burlingame**, Partner, Morgan Lewis. Boston Office
- **Maurits Geerlings**, President and CEO Nanocell Therapeutics, Inc.
- **Andrew Haupt**, Partner, Morgan Lewis. Philadelphia Office

11:35 a.m.-12:45 p.m.

Lunch Break and Networking

Lunchtime Session: CIC Lab+Innovation Campus Malvern Room

Session host **Patricia Tsao**, COO and Scientific Director, CytoEX Inc.

11:45 a.m.-12:45 p.m. **The Importance of a Shared Community for Starting & Building Your Life Science Company**

Kelly Sullivan, Ph.D., Director of Labs, CIC Lab+ Innovation Campus

Plenary Session**Grand Ballroom**

- 12:45-12:55 p.m.** **Opening Remarks:** **Lu Wang**, Ph.D., M.B.A., President-elect SAPA-GP; Conference Chair; Director, Downstream Development, Spark Therapeutics
Jin Wen, Ph.D., Sr. Scientist, Analytical Development, Spark Therapeutics
- 12:55-1:40 p.m.** **Keynote Speech: Accelerating the Cell Therapy Transformation**
Jason Bock, Ph.D., CEO, Cell Therapy Manufacturing Center
- 1:40-2:00 p.m.** **Coffee Break and Networking**

2:00-3:30 p.m. Parallel Sessions**Gene Therapy****Centennial 1****Session 2: From Rare to Common: Exploring the Evolution of Gene Therapy in Disease Treatment**

- Session chair:** **Jingwen Niu**, Ph.D., Principal Investigator, AlphaThera
- 2:00-2:30 p.m.** **Gene Therapy Targets for Diseases of the Visual System**
Gareth Thomas, Ph.D., Associate Professor, Temple University Lewis Katz School of Medicine
- 2:30-3:00 p.m.** **Evolving Gene Therapy for Common Neurological Diseases**
Lingzhi Zhao, Ph.D., VP, NeuShen Therapeutics
- 3:00-3:30 p.m.** **Panel Discussion**
Session 2 speakers

Chemistry, Manufacturing and Controls (CMC)**Grand Ballroom****Session 2: From Source to Product: Advance Quality Control for CGT Manufacturing**

- Session chair:** **Yu-Chih Hsu**, Ph.D., Director of Bioassay Development and QC, Gene Therapy Program, University of Pennsylvania
- 2:00-2:30 p.m.** **Spark Therapeutics Quality Control Strategies for: Reference Standard, External Partner Management & Operational Excellence**
Tonya Hutchison, M.B.A, Sr. Director, Quality Control Operations, Spark Therapeutics
- 2:30-3:00 p.m.** **Plasmids Sequence Purity and Analytical Considerations for rAAV Products**

Amy Gallagher, B.S., Principal Scientist Analytical & Quality Control, Spark Therapeutics

3:00-3:30 p.m.

AAVone: One Plasmid AAV Production System Solves AAV Manufacture Bottleneck Problems

Daozhan Yu, Ph.D., President and CEO, AAVnerGene

Business Track-1

Centennial 2

Session 2: Hidden Traps: What Makes Investors Walk Away from Your Pitch?

Session chair:

Michele Washko, M.B.A., M.A., President & CEO, Life Sciences Greenhouse Investments

2:00-3:30 p.m.

Panel Discussion and Q&A

Panelists:

- Jason Butler, Ph.D., Managing Director, Director of Healthcare Research, Citizens JMP
- David Kellman, BSE., Managing Director, Head of Healthcare Investment Banking, Citizens JMP
- Patrick Lundgren, Ph.D., Investor, Hummingbird Ventures
- Vikram Patra, M.B.A., Managing Director, Freedom Capital Markets
- Enna Weng, M.B.A., Managing Director, Freedom Capital Markets
- Brian Zhou, Ph.D., Associate Director, Lily Venture, Eli Lilly and Company

Business Track-2

Centennial 3

Session 2a: Navigating Talent Partnerships: Optimizing HR Outsourcing in the Evolving Cell & Gene Therapy Sector

Session chair:

Marcia Zaruba O'Connor, M.S., Founder and CEO, The O'Connor Group

2:00-3:30 p.m.

Panel Discussion and Q&A

- Meghan Popoleo, VP of Growth, The O'Connor Group
- Kim Bunting, Director of the Human Capital Consulting Practice, The O'Connor Group

Business Track-2

Malvern

Session 2b: Strategic Value Creation -Where Biotechnology Businesses Meet Project Management!!

Session chair:

TBD

2:00-3:00 p.m.

Leena Pattarkine, Ph.D., Program Lead Biotechnology, Director Capital Area Biotechnology Partnership, Harrisburg University of Science and Technology

Company Showcase

Haverford Room

Company Showcase: Qiagen

Session chair: Xinjun Zhang, Ph.D., Associate Principal Scientist, Merck

2:00-3:30 p.m. Analysis of DNA Integrity and Stability Using Digital PCR
-A Rapid Approach for Characterizing AAV Genome Integrity
Samir Afif, Ph.D., Sr. Account Manager Life Science, North America, Qiagen

3:30-3:45 p.m. Coffee Break and Networking

3:45-5:15 p.m. Parallel Sessions

Gene Therapy

Centennial 1

Session 3: The Future of Gene Therapy: Exploring Cutting-Edge Techniques and Boundless Potential

Session chair: CJ (Chunjuan) Song, Ph.D., VP, ExegenesisBio

3:45-4:15 p.m. Multiomic Sequencing in Characterization, Safety, and Quality Control of in vivo and ex vivo Cell and Gene Therapies
Kirsten Copren, Ph.D., Director, Analytical Development, National Resilience, Inc.

4:15-4:45 p.m. AI-driven Decision Making for Gene Therapy

Irene Rombel, Ph.D., M.B.A., CEO, President and Co-Founder, BioCurie

4:45-5:15 p.m. Modified AAV5 Vectors: From Underperformer to Top Performer

Bin Xiao, Ph.D., M.D., Director of R&D, Askbio. Inc.

Chemistry, Manufacturing and Controls (CMC)

Grand Ballroom

Session 3: From Process to Consequence: Enhancing Quality Assurance for Production Readiness and Approval

Session chair: Long Geng, Ph.D., Sr. Scientist, Clinical Biomarker

3:45-4:15 p.m. Moving from Research Concept to Tangible Cell Therapy Asset for Clinical Evaluation: Critical CMC Learnings

Shyam Subramanian, Ph.D., Principal, Biosynth Solutions

4:15-4:45 p.m. Overview and Progress of CAR-T Cell Therapy Manufacturing Development

Kaiyuan Jiang, Ph.D., Associate Director, Cell Therapy Process Development, Johnson & Johnson Innovative Medicine

4:45-5:15 p.m. Panel Discussion

Panelists: Afternoon speakers

Session 3: From Fundraising to Exit: How to Build a Startup's Legal Armor

Session chair: [Sima Kulkarni](#), J.D., M.S., Special Counsel, Duane Morris LLP

3:45-5:15 p.m. Panel Discussion

Panelists:

- [Rebecca Guzman](#), J.D., Partner, Vice Chair of M&A Division, Duane Morris LLP
- [Wendy Pan](#), Ph.D., J.D., Partner, Goodwin Procter LLP
- [Aliya Sanders](#), J.D., M.P.H., Partner, Gunderson Dettmer

Session 3: Digitization of GMP Documentation: Operational Impact & Lessons Learned

Session chair: [Matt Cabrey](#), Director, Ideas x Innovation Network (i2n)

Panelists:

- 3:45-5:15 p.m.**
- [Patrick Denninger](#), CEO, CellPort Software
 - [Robert Steinhagen](#), VP, Life Sciences Division, ABM Industries

5:15-6:00 p.m.

Reception

6:00-8:00 p.m.

Dinner (Invitation Only)

**Appreciation
Speech**

Yufeng Li, Ph.D., SAPA-GP president (2024-25)

AGENDA Saturday, June 15th, 8:00 a.m.-5:45 p.m.

8:00-8:45 a.m. Check in

Plenary Session

Grand Ballroom

8:45-8:50 a.m. **Opening Remarks:** **Haichen Yang**, M.D., M.B.A. Former President SAPA-GP 2022-23; Conference Advisory Committee Co-chair; VP, Clinical Research, Amicus Therapeutics

8:50-9:35 a.m. **Keynote speech: AAV Gene Tx for CNS Disorders**
Guangping Gao, Ph.D., Professor and Director, Horae Gene Therapy Center, UMass Chan Medical School

9:35-10:20 a.m. **Keynote speech: Beyond “One Disease at a Time”: Towards Therapeutic Platforms for the Treatment of Rare Monogenic Disease**
PJ Brooks, Ph.D., Deputy Director, Division of Rare Diseases Research Innovation National Center for Advancing Translational Sciences National Institutes of Health

10:20-10:40 a.m. **Coffee Break and Networking**

10:40 a.m. -12:10 p.m. Parallel Sessions

Cell Therapy

Grand Ballroom

Session 1: Innovative Cell Therapy beyond CAR-T

Session chair: **Shuai Dong**, Ph.D., Sr. Manager, Quantitative Clinical Pharmacology, Sarepta Therapeutics

10:40-11:10 a.m. **TIL Immunotherapy for Solid Tumors**

Hequn Yin, Ph.D., SVP & Head of Research, Iovance Biotherapeutics

11:10-11:40 a.m. **Discovery of a Multi-Engineered iPSC-Derived Cell Therapy Product**

Michael Naso, Ph.D., SVP, Century Therapeutics

11:40 a.m.-12:10 p.m. **The Progress and Challenge of Cell Therapy Targeting CNS Diseases**

Jing Fan, Ph.D., Founder, President & CEO, Hopstem Bio

Clinical Development and Regulatory

Centennial 1

Session 1: Unique Challenges of Clinical Development for Gene Therapy

Session chair: **Mitra Tavakkoli**, M.D., Pharm.D., Independent Sr. Clinical Consultant

- 10:40-11:10 a.m.** **Data-Sharing to Improve Safety and Efficiency in Gene Therapy Clinical Development**
 Genevieve (Jenny) Laforet, M.D., Ph.D., SVP, Clinical Development, Aspa Therapeutics/BridgeBio Gene Therapy
- 11:10-11:40 a.m.** **Placebo Control Arms in Rare Disease Clinical Trials: Main Considerations**
 Mitra Tavakkoli, M.D., Pharm.D, Independent Sr. Clinical Consultant
- 11:40 a.m.-12:10 p.m.** **Imlifidase as a Pre-treatment to Enable AAV based Gene Therapy in Patients with Antibodies Towards the Vector**
 Lena Winstedt, Ph.D., Global Franchise Lead Gene Therapy, Hansa Biopharma AB

RNA and Gene Editing Therapy

Centennial 3

Session 1: The Next-Gen CRISPR and the Future of Gene Editing

- Session chair:** Tao Niu, Ph.D., Director, Quantitative Clinical Pharmacology, Sarepta Therapeutics
- 10:40-11:10 a.m.** **Next-Generation CRISPR Gene-Editing Technology for Drug Development**
 Alvin Luk, Ph.D., MBA., CCRA, Co-founder and CEO, HuidaGene
- 11:10-11:40 a.m.** **An Innovative Technology for High Yield and More Stable CRISPR Guide RNA**
 Xiulian Sun, Ph.D., CTO, uBriGene
- 11:40 a.m.-12:10 p.m.** **Transform DMD through Base Editing Technology**
 Chunyan He, Ph.D., CEO, Suzhou GenAssist Therapeutic

Business

Centennial 2

Session 1: Using Strategic Partnerships, Licensing, and Venture Financing to Get to Your Next Critical Value Inflection Point

- Session chair:** Lisa Baskin, B.S., SVP of Scientific Real Estate, Scheer Partners
- Panelists:**
- Hugh Davis, Ph.D., CB&DO, President, Biosion USA, Inc.
 - Sean Fu, Ph.D., M.B.A., Operating Partner, ABio-X
 - Sunil Joshi, M.B.A., M.S., President, Strategius Consultants
 - Marian Nakada, Ph.D., VP of Venture Investments J&J Innovation-JJDC
- 10:40 a.m.-12:10 p.m.**

- [Heather Rose](#), Ph.D., J.D., VP of Technology Licensing and Start-ups, Thomas Jefferson University & Jefferson Health

12:10-1:30 p.m.

Lunch Break and Networking

Lunchtime Session: AAVnerGene

Malvern Room

Session host Ying Zhou, Ph.D., M.B.A., Analytical Program Steward, Teva Pharmaceuticals

12:25-1:25 p.m. **Capsid Engineering and Screening Platform Developed New AAV for Different Organs**

Daozhan Yu, Ph.D., CEO, AAVnerGene

Lunchtime Session: Finnegan Henderson

Paoli Room

Session host Hui Wang, Ph.D., Head of US Business Development, Genevoyager

12:25-1:25 p.m. **IP Considerations for Gene & Cell Therapy**

Yieyie Yang, Ph.D., J.D., Partner, Finnegan Henderson

Lunchtime Session: uBriGene.

Frazer Room

Session host Haichen Nie, Ph.D., Associate Director, Teva Pharmaceuticals

12:25-1:25 p.m. **How Could CDMO and Technology Innovations make CGT Affordable?**

Xiulian Sun, Ph.D., CTO, uBriGene

1:30-3:00 p.m. Parallel Sessions

Cell Therapy

Centennial 1

Session 2: Current Understanding and Management of Toxicities for Cell Therapy

Session chair: [Jake Dong](#), Ph.D., Scientist, Cell Therapy, Johnson & Johnson Innovative Medicine

1:30-2:00 p.m. **Hybrid CAR T Cells with Engineered Fuel Flexibility**

[Roderick O'Connor](#), Ph.D., Research Assistant Professor, Perelman School of Medicine, University of Pennsylvania

2:00-2:30 p.m. **Nonclinical Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products**

[Gregory Conway](#), Ph.D., Pharmacology/Toxicology Reviewer, Office of Therapeutic Products, CBER, FDA

2:30-3:00 p.m. **Mitigation Strategies to Address Potential Genomic Safety Risks of Allogenic Cell Therapy**
Ilayaraja Muthuramu, Ph.D., Sr. Scientist, Johnson and Johnson

Clinical Development and Regulatory

Centennial 2

Session 2: Clinical & Regulatory Considerations for Cell Therapy in Hematology & Oncology

Session chair: Yan Ni, Ph.D., Executive Director, Passage Bio

1:30-2:00 p.m. **Catch Me if You Can: Resistance to CART Immunotherapy**
Marco Ruella, M.D., Assistant Professor of Medicine, Division of Hematology and Oncology and Center for Cellular Immunotherapies, University of Pennsylvania

2:00-2:30 p.m. **Comprehensive Clinical Pharmacology of Lisocabtagene Maraleucel for B-cell Malignancies**
Ken Ogasawara, Ph.D., MPH, Director Clinical Pharmacology and Pharmacometrics, Bristol Myers Squibb

2:30-3:00 p.m. **Clinical Pharmacology Considerations for CAR T Cell Therapy – a Regulatory Perspective**
Xiaofei Wang, Ph.D., Sr. Clinical Pharmacology Reviewer, Office of Therapeutic Products, CBER, FDA

RNA and Gene Editing

Centennial 3

Session 2: Bioanalytical, DMPK and Clinical Pharmacology Strategies for In Vivo Characterization of Nucleic Acid Therapy

Session chair: Peixin Zhu, Ph.D., VP, Editing Development, Verve Therapeutics

1:30-2:00 p.m. **Characterizing ADME Properties of Lipid Nanoparticle (LNP) Encapsulated mRNA Therapeutic and Vaccine**
Wenying Jian, Ph.D., Director, Bioanalytical Discovery and Development Sciences, Johnson & Johnson Innovative Medicine

2:00-2:30 p.m. **A Bioanalytical Strategy for the Antisense Oligonucleotide**
Xinqun Irene Wu, M.S., Sr. Scientist, Clinical Pharmacology, Pharmacometrics, Disposition & Bioanalysis, Bristol Myers Squibb

2:30-3:00 p.m. **Predicting Clinical PK/PD and Impacts of Organ Impairment to Support Clinical Development of siRNA-based Therapeutics Using a**

Mechanistic Physiologically Based Pharmacokinetic and Pharmacodynamic (PBPK-PD) Platform Model

Annie Lumen, Ph.D., Scientific Associate Director, Clinical Pharmacology Modeling and Simulation, Amgen

Business

Frazer Room

Session 2: From the Bench to the Board Room: Navigating the World of Entrepreneurship, Innovation and Corporate Venture Capital in the Biotech Industry

Session chair: Bill Lu, M.B.A., Principal Consultant, Forerun Advantage

1:30-2:30 p.m. Speaker: Marian Nakada, Ph.D., VP of Venture Investments J&J Innovation-JJDC

3:00-3:15 p.m. Coffee Break and Networking

3:15-4:45 p.m. Parallel Sessions

Clinical Development and Regulatory

Centennial 2

Session 3: TBD

Session chair: Tao Niu, Ph.D., Director, Quantitative Clinical Pharmacology, Sarepta Therapeutics

3:15-3:45 p.m. Considerations for Immunogenicity Assessment in AAV-based (in-vivo) Gene Therapy (GTx) Development

Emmanuel Adu-Gyamfi, Ph.D., Director, Global Regulatory Sciences (Gene and Cell Therapy), Bristol Myers Squibb

3:45-4:15 p.m. Title: TBD

Yingjie (Jason) Huang, M.D., CMO, XlifeSc Ltd.

4:15-4:45 p.m. Comparison of Assay Performance Between Quantitative qPCR and a Nanoplate Based dPCR for use in Biodistribution Studies

Yanchun Li, Ph.D., Sr. Scientist, Johnson & Johnson

Business

Grand Ballroom

Session 3: Talk-To-An-Investor

Session chair: Austin Duke, Ph.D., Managing Director, BroadOak

Investor/advisors:

- Austin Duke, Ph.D., Managing Director, BroadOak
- James Fendrick, B.S., President & CEO, Rockland Immunochemicals
- Glenn Gaddy, Ph.D., Managing Member, Robin Hood Ventures
- Paul Hoerbelt, Ph.D., Director, Biotechnologies, Research Corporation Technologies

- [Gregory Jackson](#), EVP, Life Science Greenhouse Investments
- [Rick Jones](#), M.D., M.B.A., Partner, BioAdvance
- [Steve Manobianco](#), M.B.A., Managing Director, PSG Life Sciences
- [Bryan Poltilove](#), M.B.A., Consultant, BroadOak Capital Partners
- [Heather Steinman](#), Ph.D., M.B.A., SVP, Business Development & Executive Director, Technology Transfer at The Wistar Institute

World Cafe Chat - Networking, Q&A

4:45-4:50 p.m.

Concluding Remarks and Raffle Draw

4:50-5:45 p.m.

Reception