

RegenBio Summit: Transforming Next-Gen Biotherapeutics 2024

Ponte Vedra Beach, Florida

December 9, 2024 to December 11, 2024

Eastern Standard Time

Day 1 Monday, December 9, 2024

8:00 AM **Breakfast, Registration & Exhibits**

9:00 AM **Welcome Announcements**
Julie G. Allickson, Ph.D. and Saranya P. Wyles, M.D., Ph.D.

9:15 AM **Keynote: Regulating Regenerative Therapies from IND to BLA**
Peter Marks, M.D., Ph.D.

9:30 AM **Fireside Chat: Mistakes and Lessons Learned from FDA CBER Director's Desk. An Insight into Accelerated Approval Pathways**
Moderator: Julie G. Allickson, Ph.D.

10:00 AM **Genetically Engineered Cells Panel**
Moderators: Michael P. Gustafson, Ph.D.

10:30 AM **Break and Exhibits**

Tissue Engineering Plenary

Moderators: David G. Lott, M.D. and Anthony J. Windebank, M.D.

11:00 AM **Sculpting Sound: 3D Bioprinting the Larynx**
David G. Lott, M.D.

11:15 AM **Can We Grow a Personalized Heart**
Doris Taylor, Ph.D.

11:30 AM

To be announced

11:45 AM

Biologically Inspired Engineering Strategies to Treat Vascular Injury and Tissue Fibrosis

Jae-Won Shin, Ph.D.

12:00 PM

Panel Discussion

12:30 PM

Fireside Chat: Exosomes, Are We There Yet?

Atta Behfar, M.D., Ph.D.

1:00 PM

Lunch

2:30 PM

Fireside Chat: Impact of Generative Artificial Intelligence on Cell and Gene Therapy

Moderator: Peter A. Noseworthy, M.D., M.B.A.

Joel Greshock

3:00 PM

To be announced

3:10 PM

Writing DNA with RNA: Genome Engineering by Target Primed Reverse Transcription

Mandhusudan Peshwa, Ph.D.

3:20 PM

To be announced

3:30 PM

Break and Exhibits

4:00 PM **Defining the Issues: FDA Approach to Centralized,
Decentralized, and Point of Care Manufacturing**
Richard McFarland, M.D., Ph.D.

4:30 PM **To be announced**

5:00 PM **Closing Comments**

5:30 PM **Welcome Reception**

Day 2

Tuesday, December 10, 2024

8:00 AM

Breakfast with Experts

FDA Unveiled: Navigating U.S. Regulations and Regulators

Drew M. Witter, M.S., RAC

Harmonizing Excellence: A Global Odyssey to Meet GMP Requirements

Richard McFarland, M.D., Ph.D.

Process Development 101

Cynthia E. Wilkins, Ph.D.

Advanced Biomanufacturing 101

Snigdha Rai

Quality Control 101

Tony W. DeFusco

Quality Assurance 101

Cameron E. Jones

9:30 AM

Fireside Chat: iPSC Readiness

Dennis Wigle, M.D., Ph.D. and Timothy Nelson, M.D., Ph.D.

10:00 AM

Morning Break

- 10:30 AM **Keynote: Trial of Beremagene Geperpavec (B-VEC) for Dystrophic Epidermolysis Bullosa – First FDA-Approved Topical Gene Therapy**
M. Peter Marinkovich, M.D.
- 10:50 AM **Fireside Chat: Mistakes and Lessons Learned from Startups. An Insight into the Success Path of Krystal Biotech, Inc.**
Moderator: Saranya P. Wyles, M.D., Ph.D.
- 11:15 AM **Business of Regenerative Medicine**
Manu Nair
- 11:40 AM **Mayo MedTech Accelerator: The Future of Cell and Gene Therapy**
Marianne Van Der Steen
- 12:00 PM **Lunch/Exhibits**

Cell and Gene Therapy Plenary

Moderator: Maliha Zahid, M.B.B.S., Ph.D. and Sanjay Misra, M.D.

- 1:30 PM **Gene or Cell Therapy for Cardiovascular Applications**
Sanjay Misra, M.D.
- 1:45 PM **To be announced**
- 2:00 PM **To be announced**
- 2:15 PM **The Allure of Biomanufacturing Tregs for Inflammatory Bowel Disease**
William Faubion, M.D.

2:30 PM **Panel Discussion**

3:00 PM **Afternoon Break**

3:30 PM **Healthcare Innovation – Think Tank Fast Pitch**
Charles J. Bruce, M.B., Ch.B.

5:00 PM **Poster Session & Networking**

6:00 PM **Adjourn**

Day 3 **Wednesday, December 11, 2024**

8:00 AM **Breakfast and Exhibits**

9:00 AM **Keynote: Exploring the Promise of CRISPR Therapeutics In Vivo and Cell Therapy Applications**
Birgit Schultes, Ph.D.

9:30 AM **To be announced**

10:00 AM **Roundtable: Opportunities and Challenges for Regenerative Healthcare in the Future**
Moderator: Julie Allickson, Ph.D.
Miguel Forte, Ph.D.

10:30 AM **Panel: Ethics in Regenerative Biotherapeutics**
Moderators: Michelle McGowan, Ph.D. and Megan Allyse, Ph.D.

11:15 AM **Morning Break**

iPSC Therapy Plenary

11:30 AM **To be announced**

11:45 AM **A Vision to Grow Stem Cells into Retinal Pigment Epithelium (RPE) for Eyesight**
Kapil Bharti, Ph.D.

12:00 PM **To be announced**

12:15 PM **Panel Discussion**

12:30 PM **Lunch and Exhibits**

Immunotherapy Plenary

Moderators: Saad J. Kenderian, M.B., Ch.B.

1:30 PM **Current Challenges in CAR-T Cell Therapy and Role of Tumor Microenvironment**
Saad J. Kenderian, M.B., Ch.B.

1:45 PM **Transforming Lives with Personalized Cancer Therapies**
Bruce Levine, Ph.D.

2:00 PM **Managing CAR-T Cell Therapy in the Real World**
Yi Lin, M.D., Ph.D.

2:15 PM **Panel Discussion**

2:30 PM **Addressing Challenges in Translation and Commercialization of Cell and Gene Therapies**
Uma Lakshmipathy, Ph.D.

3:00 PM **Adjourn**