

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.

10:00 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.

10:30 AM **Laryngeal Transplantation and Regeneration: Breaking the Silence**

David G. Lott, M.D.

11:00 AM **Break and Exhibits**

11:30 AM **Fireside Chat: Impact of Generative Artificial Intelligence on Cell and Gene Therapy**

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

12:00 PM **Lunch**

1:00 PM **Plenary Highlight: Can we Grow a Personalized Heart**

Doris Taylor, Ph.D., FACC, FAHA

Tissue Engineering Plenary

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

- | | |
|---------|---|
| 1:30 PM | 3D Bioprinting Skin
Saranya P. Wyles, M.D., Ph.D. |
| 1:45 PM | Biologically Inspired Engineering Strategies to Treat Vascular Injury and Tissue Fibrosis
Jae-Won Shin, Ph.D. |
| 2:00 PM | Fireside Chat: Exosomes, Are We There Yet?
Atta Behfar, M.D., Ph.D. |
| 2:30 PM | Defining the Issues: FDA Approach to Centralized, Decentralized, and Point of Care Manufacturing
Richard McFarland, M.D., Ph.D. |
| 3:00 PM | Break & Exhibits |
| 3:30 PM | To be announced |
| 4:00 PM | To be announced |
| 4:30 PM | To be announced |
| 5:00 PM | Closing Comments |
| 5:30 PM | Welcome Reception |

Day 2

Tuesday, December 10, 2024

8:30 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

Break & Exhibits

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**
- 1:00 PM **From the Desk of Mayo Clinic Center for Regenerative Biotherapeutics Medical Director**
William Faubion, M.D.
- Cell and Gene Therapy Plenary**
Moderator: Maliha Zahid, M.B.B.S., Ph.D. and Sanjay Misra, M.D.
- 1:30 PM **Role of Stem Cells in Vascular Injury**
Sanjay Misra, M.D.
- 1:45 PM **The Allure of Biomanufacturing Tregs for Inflammatory Bowel Disease**
William A. Faubion Jr, M.D.
- 2:00 PM **To be announced**
- 2:15 PM **To be announced**
- 2:30 PM **Fireside: Addressing Challenges in Translation of CGT**
Uma Lakshmiathy, Ph.D.

3:00 PM **Break**

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

To be announced

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

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

Fireside Chat: Mistakes and Lessons Learned from Startups. An insight into the success path of Intellia Therapeutics, Inc.

Maggie A. DiGuardo, M.D.

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.

11:00 AM

Break & Exhibits

11:30 AM

Plenary Highlight: Transforming Lives with Personalized Cancer Therapies

Bruce L. Levine, Ph.D.

12:00 PM

Lunch & Exhibits

iPSC Therapy Plenary

1:00 PM

A Vision to Grow Stem Cells into Retinal Pigment Epithelium (RPE) for Eyesight

Kapil Bharti, Ph.D.

- 1:15 PM **To be announced**
- 1:30 PM **To be announced**
- 1:45 PM **Panel Discussion**
Zachary Resch Ph.D.
- 2:00 PM **Mayo Clinic Highlight**
Saad J. Kenderian, M.B., Ch.B.
- 2:30 PM **Fireside Chat: Immunotherapy**
Yi Lin, M.D., Ph.D.
- 3:00 PM **Closing Remarks**
Julie G. Allickson, Ph.D., & Saranya P. Wyles, M.D., Ph.D.
- 3:10 PM **Mayo Clinic Florida – Regenerative Clinical Trial Portfolio**
- Regenerative Rehabilitation**
Wenchun Qu, M.D., Ph.D.
- Regenerative Nephrology**
LaTonya J Hickson, M.D.
- Regenerative Pulmonology**
Jorge M. Mallea, M.D.
- Regenerative Dermatology**
Katherine J. Bodiford, M.D.
- Regenerative Orthopedics**
Shane A. Shapiro, M.D.
- Regenerative Vascular Surgery**
Sam Farres, M.D.