

# 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**

## **Regenerative Orthopedics: From Care to Cure**

Moderators: Brennan J. Boettcher, D.O.; Daniel B. F. Saris, M.D., Ph.D.; and Jacob L. Sellon, M.D.

- 3:30 PM            **Hip RECLAIM: A Phase I Safety and Feasibility Trial of REcycled Cartilage Auto/Allo IMplantation for the Treatment and Repair of Focal Hip Cartilage Defects**  
TBD
- 4:00 PM            **Musculoskeletal/Orthopedic**  
TBD
- 4:30 PM            **Demonstration-From Discovery to Patient**  
Senior Directors

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**

Craig Hasilo

**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: 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 **CELLTOP: An Update from Autologous Adipose Derived Mesenchymal Stem Cells in the Treatment of Paralysis due to Traumatic Spinal Cord Injury**  
Mohamad Bydon, M.D.

2:15 PM **Phase Ib/II Study of Autologous Dendritic Cell Therapy Delivered Intratumorally after Cryoablation in Combination with Pembrolizumab for Patients with Metastatic or Unresectable Melanoma**  
Matthew S. Block, M.D., Ph.D.

2:30 PM **Fireside: Addressing Challenges in Translation of CGT**  
Uma Lakshmipathy, 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**  
Rupa Pike, Ph.D.

**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**

Moderator: Zachary Resch, PhD

1:00 PM

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

Kapil Bharti, Ph.D.

- 1:15 PM **TBD**  
Quinn P. Peterson, Ph.D.
- 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.