



Anthony Atala MD
 Director, Wake Forest Institute for Regenerative Medicine



Joan Schanck MPA
 Chief Education Program Officer, Wake Forest Institute for Regenerative Medicine



Matthew Porteus MD PhD
 Professor, Pediatrics, Stanford School of Medicine; Professor, Institute of Stem Cell Biology



Patricia Nano PhD
 Post-Doc Fellow, University of California, Los Angeles, Bhaduri Lab



Graca Almeida-Porada MD, PhD
 Professor, Wake Forest Institute for Regenerative Medicine



Janet Zoldan PhD
 Associate Professor, University of Texas, Austin



Abraham Joy PhD
 Professor and Dept. Chair, Bioengineering, Northeastern University



Antonios G. Mikos PhD
 Professor, Bioengineering and Chemical and Biomolecular Engineering, Rice University



Xizuhi Susan Sun PhD
 Professor, Wake Forest Institute for Regenerative Medicine



Ryan Felix PhD
 Pre-Doctoral Fellow, University of Maryland



Frank Marini PhD
 Professor, Wake Forest Institute for Regenerative Medicine



Robert Newman PhD
 Biochemist, Molecular Biologist, North Carolina Agricultural and Technical State University



Ritu Raman PhD
 Associate Professor, Mechanical Engineering, MIT



Christopher Porada PhD
 Professor, Wake Forest Institute for Regenerative Medicine



John Tisdale MD
 Senior Investigator, Chief of Cellular and Molecular Therapeutics, NIH



Josh Maxwell PhD
 Assistant Professor, Wake Forest Institute for Regenerative Medicine



Bruce Culleton MD
 Chief Executive Officer, ProKidney



Victoria Weis PhD
 Assistant Professor, Wake Forest Institute for Regenerative Medicine

WELCOME AND OPENING

- 8:20—8:30am **Welcome and Introduction**
Joan Schanck, MPA
- 8:30—9:10am **Regenerative Medicine: Current Concepts and Changing Trends**
Anthony Atala, MD

SESSION 1: PLURIPOTENT STEM CELLS AND PROGENITORS

- 9:10—9:30am **XXX**
Matthew Porteus, MD, PhD
- 9:30—9:50am **Organoid-Based Approaches to Perturb and Observe the Human Brain**
Patricia Nano, PhD
- 9:50—10:10am **Fulfilling the Promise of Pluripotent Stem Cells**
Janet Zoldan, PhD
- 10:10—10:30am **Moderated Panel**
Joan Schanck, MPA
- Break & Networking***

SESSION 2: BIOMATERIALS

- 10:45—11:05am **Bridging the Gap Between Natural and Synthetic Biomaterials: Illustrative Example of a Peptidomimetic Polyester Platform**
Abraham Joy, PhD
- 11:05—11:25am **Particulate and Granular Hydrogels for Tissue Engineering**
Antonios G. Mikos, PhD
- 11:25—11:45am **Advanced Synthetic Hydrogels Enabled Physiologically Relevant Organoids**
Xizuhi Susan Sun, PhD
- 11:45am—12:05pm **Relevant Organoids and Engineered Organ Tissues**
Ryan Felix
- 12:05—12:20pm **Moderated Panel**
Susan Sun, PhD

Lunch Break with Trainees' Careers Perspectives Session I: Academia and Exhibiting

DAY 1

SESSION 3: ENABLING TECHNOLOGIES

- 1:30—1:50pm **Making Regeneration Visible: Imaging Cells, Tissues to Spatial Systems**
Frank Marini, PhD
- 1:50—2:10pm **Next-Generation Genetically Encoded Activity Reporters for Real-Time Tracking of Kinase Signaling in Living Cells and Organoids**
Robert Newman, PhD
- 2:10—2:30pm **Tissue Engineering Functional Models of the Neuromuscular System**
Ritu Raman, PhD
- 2:30—2:50pm **Novel Antibody Drug Conjugates And Their Role In Prenatal Hematopoietic Stem Cell Transplantation For Genetic Disorders**
Graca Almeida-Porada, MD, PhD
- 2:50—3:10pm **Gene Therapy And Gene Editing: The Promise Of A Permanent Cure Following A Single Treatment**
Christopher Porada, PhD
- 3:10—3:30pm **Moderated Panel**
Joan Schanck, MPA

Break & Networking

SESSION 4: CELL THERAPIES

- 3:30—3:50pm **Gene Therapy For Sickle Cell Disease, From Concept To FDA Approval**
John Tisdale, PhD
- 3:50—4:10pm **Next Generation Stem Cell Therapies for the Heart**
Josh Maxwell, PhD
- 4:10—4:30pm **Advancing Cell Therapy in Chronic Kidney Disease**
Bruce Culleton, MD
- 4:30—4:50pm **Placental Stem Cell Based Therapy for Necrotizing Enterocolitis in the Premature Infant**
Victoria Weis, PhD
- 4:50—5:05pm **Moderated Panel**
Josh Maxwell, PhD

Opening Reception and Networking with Open Exhibit Hall



James Yoo MD PhD
Professor, Wake Forest Institute for Regenerative Medicine



Chandan K. Sen PhD
Chair and Director, McGowan Institute for Regenerative Medicine, University of Pittsburgh



Yu Shrike Zhang PhD
Associate Professor, Harvard Medical School; Associate Bioengineer, Brigham and Women's



Steve Bauer PhD
Chief Regulatory Science Affairs Program Officer, Wake Forest Institute for Regenerative Medicine



Amber Aagaard PhD
Director, Quality & Regulatory Assurance
Corning Life Sciences



John Huang PhD
Founder and CEO, TheWell Bioscience, Inc.



Alicia Henn PhD
Chief Scientific Officer, BioSpherix LLC



Adam Samson PhD
President, Advocate Health National Center for Clinical Trials



Kyung Sung PhD
Chief, Cellular and Tissue Therapeutics Branch, FDA



Stephen Sawyer PhD
Associate Professor, Wake Forest Institute for Regenerative Medicine



Zubin Master PhD
Associate Professor, Wake Forest Institute for Regenerative Medicine



Jan Nolta PhD
Director, Cell and Gene Therapy, University of California Davis School of Medicine



Jacob Koffler PhD
Assistant Professor, Neurosciences, UC San Diego School of Medicine; CEO, Auxilium Biotechnologies



Vijay Gorantla MD PhD
Professor, Wake Forest Institute for Regenerative Medicine

8:50—9:00am **Welcome and Overview**
Joan Schanck, MPA

SESSION 5: TISSUE ENGINEERING MEDICAL PRODUCTS

9:00—9:20am **Considerations for Developing Tissue Engineered Medical Products**

James Yoo, MD, PhD

9:20—9:50am **Tissue Nanotransfection Technology: Vasculogenic Reprogramming of the Skin In Vivo**

Chandan K. Sen, PhD

9:50—10:10am **Bioprinting: from Technologies to Applications**

Yu Shrike Zhang, PhD

10:10—10:30am **Moderated Panel**

James Yoo, MD, PhD

Break & Networking

SESSION 6: REGULATORY AND INDUSTRY PERSPECTIVES ON RM MANUFACTURING

10:45—11:00am **Navigating the Regulatory Landscape for Regenerative Medicine Products**

Steve Bauer, PhD

11:00—11:10am **Developing Reagents, Equipment, and Bioreactors through Regenerative Medicine Product Development**

Amber Aagaard, PhD

11:10—11:20am **Development Of Xeno-Free, Gmp Grade Hydrogels For Regenerative Medicine**

John Huang, PhD

11:20—11:25am **Q&A**

11:25—11:35am **Cell Therapy Manufacturing: Cytocentric Approaches**

Alicia Henn, PhD

11:35am—12:00pm **FDA Perspectives on Microphysiological System Development and Use**

Kyung Sung, PhD

12:00—12:15pm **Moderated Panel**

Stephen Sawyer, PhD

Lunch Break with with Trainees Careers Perspectives Session II: Industry and Open Exhibit Hall

SESSION 7: CLINICAL TRIALS AND BIOETHICS

- 1:15—1:35pm **Scaling Regenerative Medicine Ethically: The Clinical Trial Infrastructure Challenge**
Adam Samson, PhD
- 1:35—1:55pm **Some Legit, Some Illegit: How Patients Access Scientifically Unproven Regenerative Products**
Zubin Master, PhD
- 1:55—2:15pm **Working Toward Improving Accessibility And Affordability In Cell And Gene Therapy**
Jan Nolta, PhD
- 2:15—2:35pm **Neurospan-1: A Clinical Trial Demonstrating the Impact of Organized Axonal Regeneration on Outcomes After Peripheral Nerve Injury**
Jacob Koffler, PhD
- 2:35—2:55pm **Clinical Trials at the Edge of Innovation: Designing Studies for Regenerative Surgery and Complex Transplantation**
Vijay Gorantla, MD, PhD
- 2:55—3:15pm **Moderated Panel**
Vijay Gorantla, MD, PhD

Exhibiting, Networking, Refreshments with Optional WFIRM Lab Tours



Tim Kelly PhD
CEO, RoosterBio Inc.



Laura Niklason MD PhD
Founder, President, CEO, Humacyte, Inc.; Professor, Yale University



Jeanne Loring PhD
Professor, Founding Director, Center for Regenerative Medicine, Scripps Research



Xu Han PhD
Founder, President, CryoCrate, LLC



Josh Hunsberger PhD
Chief Technology Officer, RegenMed Development Organization



Jana Stoudemire
In-Space Solutions, Axiom Space



Nirmala Pol PhD
Founder, CEO, Panache AI



Josh Han
Director, Emerging Technologies, Advocate Health Enterprise Imaging Services



Gail Nolan PhD
CEO, Puerto Rico 5G Zone; Blockchain Ignition Lab4



Shelton Charles PhD
Interim Vice President, Transfer Excellence & Success, Forsyth Technical Community College



John Chuckalovcak
Associate Director, Business Development and Partnerships, QIAGEN



Shay Soker PhD
Professor, Wake Forest Institute for Regenerative Medicine



Nilay Charkaborty PhD
Director of Cryobiology, Principal Scientist, ATCC



Tiago Lopes PhD
Founder and CEO, Nezu Biotech



Chris Puhl PhD
Business Development Manager, ExoBiosphere



Tim Dobroski
PhD Candidate, Biomedical Engineering, Virginia Tech-Wake Forest University School of Biomedical Engineering



Pinar Mesci PhD
Global Head, Biomufacturing and Biotechnology, Axiom Space



Michael Roberts PhD
Chief Scientist, ISS National Laboratory



Stefanie Countryman
Director, BioServe Space Technologies; Research Associate, University of Boulder



Kevin Engleburt
Manager, NASA In Space Production Applications



Jacob Koffler PhD
Assistant Professor, Neurosciences, UC San Diego School of Medicine; CEO, Auxilium Biotechnologies

8:20—8:30am **Welcome and Overview**
Joan Schanck, MPA

SESSION 8: COMMERCIALIZATION

9:00—9:20am **Scalable, Cost-Effective Manufacturing of Mesenchymal Stem Cell and Exosome Based Therapeutics**
Tim Kelly, PhD

9:20—9:40am **Considerations for Commercial-Scale Tissue Production**
Laura Niklason, MD, PhD

9:40—10:00am **Fulfilling The Promise Of Pluripotent Stem Cells**
Jeanne Loring, PhD

10:00—10:20am **From Glycoengineering to Global Biobanking and Biopreservation**
Xu Han, PhD

10:20—10:35am **Moderated Panel**
Joan Schanck, MPA

Break & Networking

SESSION 9: BUILDING THE INFRASTRUCTURE FOR THE NEW ERA

10:45—10:50am **Opening Remarks**
Josh Hunsberger, PhD and Jana Stoudemire

10:50—11:15am **Immersive Technologies and Disruptive Platforms Advancing Next Gen Trials**

- ▶ Nirmala Pol, PhD
- ▶ Josh Tan
- ▶ Gail Nolan, PhD
- ▶ Shelton Charles, PhD
- ▶ Cheryl Burrell
- ▶ Olivia Razzak

11:15—11:45am **Disruptive Technologies Advancing New Approach Methodologies (NAMs)**

- ▶ Stefanie Countryman
- ▶ Shay Soker, PhD
- ▶ Nilay Charkaborty, PhD
- ▶ Tiago Lopes, PhD
- ▶ Chris Puhl, PhD

Lunch Break with Open Exhibit Hall

SESSION 10: BUILDING THE INFRASTRUCTURE FOR THE NEW ERA

1:00—1:05pm

Opening Remarks

Josh Hunsberger, PhD and Jana Stoudemire

1:05—2:30pm

Building the Infrastructure of the New Era of Regenerative Medicine

- ▶ Jana Stoudemire
- ▶ Tim Dobroski, PhD
- ▶ Pinar Mesci, PhD
- ▶ Michael Roberts, PhD
- ▶ Stefanie Countryman
- ▶ Kevin Engelbert
- ▶ Jacob Koffler, PhD

2:30—2:45pm

Closing Remarks

Joan Schanck, MPA and Anthony Atala, MD