5th Annual
Regenerative Medicine Essentials:
From the Fundamentals to the Future

June 4–8, 2018
Wake Forest Bowman Gray Center for Medical Education, Winston-Salem NC
Welcome to Regenerative Medicine Essentials 2018

On behalf of the course organizing committee and our prominent group of course instructors, we welcome all of you to the 5th Annual Regenerative Medicine Essentials: From the Fundamentals to the Future course.

Often referred to as the next evolution of modern health care, regenerative medicine touches many disciplines -- from clinical care and engineering to basic science and bioethics. This one-week course, the “official course of the Regenerative Medicine Foundation”, taught by prominent experts in the field, addresses the interdisciplinary nature of regenerative medicine and provides attendees a firm foundation in this exciting field, insight into current challenges as well as a glance to the future.

In partnership with the Regenerative Medicine Foundation, the organizing committee has put together a dynamic and informative course that covers the “essential” topics and fundamental principles and current progress in tissue engineering and regenerative medicine, including stem cells and cell therapy, biomaterials, technology-based tissue engineering and enabling technologies, as well as regulatory, ethical, economic issues critical to the field. We are also excited to offer a new session, Regenerative Rehabilitation, held in partnership with the Alliance for Regenerative Rehabilitation Research and Training. We also offer three Into the Lab pre- and post-course workshops. These workshops provide hands-on interaction and demonstrations with cutting-edge technologies and techniques for regenerative medicine applications. Participants will have an opportunity to review and interact with these technologies and leading researchers at WFIRM. Workshops are also designed to provide translational and commercial insight regarding these technologies and will highlight some of the current challenges and discuss potential approaches to overcome technical hurdles.

Our instructors, which include faculty from the Wake Forest Institute for Regenerative Medicine as well as distinguished, prominent experts in the field from industry, academia and the government who join us from across the globe, provide attendees a strong foundation along with insights into future directions and potential applications of tissue engineering and regenerative medicine. Further, the 1-week course is a dynamic event, providing an ideal setting for academic, clinical, industry and government professionals to network with colleagues, encouraging formation of new exchanges, collaborations and learning opportunities.

We hope this course will further interactions among basic scientists engaged in discovery and development, translational researchers who bring laboratory discoveries to the clinical forefront, clinicians and those engaged with funding, regulatory and commercialization endeavors.

We look forward to an exciting, enjoyable and productive course for all.

Anthony Atala, MD
Director, WFIRM
RME 2018 Course Director

Joan F. Schanck, MPA
Academic Research Program Officer, WFIRM
RME 2018 Course Co-Director
With Special Thanks and Recognition

Organizing Committee

Anthony Atala, MD
RME 2018 Course Director,
Director, WFIRM

Bernard Siegel, JD
RME 2018 Course Co-Director,
Executive Director, Regenerative Medicine Foundation

Joan F. Schanck, MPA
RME 2018 Course Co-Director,
Academic Research Program Officer, WFIRM

Joanne Gray
Education and Outreach Coordinator, WFIRM

Emily McKenzie Gregg
Web and Social Media Manager, WFIRM

Taylor Dickerson
RME 2018 Program Coordinator, WFIRM

Workshop Leaders and Committees

Introduction to Translation
Julie Allickson, PhD
Director, Regenerative Medicine Clinical Center, WFIRM

Cynthia Wilkins-Port, PhD, MBA
Assoc. Dir. Process Dev., WFIRM

Lisa Hinshaw
Project Manager I, WFIRM

Darren Hickerson, MS, MDiv
Asst. Director, Manufacturing, WFIRM

Todd Meinecke, MBA
Asst. Director, Quality Assurance, WFIRM

Bioprinting Basics
John Jackson, PhD
Associate Professor, WFIRM

Ricky Solorzano
Cofounder and CEO, Allevi

Carlos Kengla, PhD
Research Associate, WFIRM

Ashkan Shafiee, PhD
Post-Doctoral Fellow, WFIRM

Sang Jin Lee, PhD
Associate Professor, WFIRM

Peter Prim, PhD
Research Fellow, WFIRM

Anil Kumar, PhD
Research Associate, WFIRM

Body-on-a-Chip
Aleksander Skardal, PhD
Assistant Professor, WFIRM

Sean Murphy, PhD
Assistant Professor, WFIRM

Julio Aleman Hernandez
Research Lab Technician, WFIRM

Mahesh Devarasetty, PhD
Research Fellow, WFIRM

Andrea Mazzocchi
PhD Student, WFIRM

Hema Sivakumar
Research Lab Technician, WFIRM

Riccardo Tamburrini, MD
Post-Doctoral Fellow, WFIRM

Goodwell Nzou
PhD Candidate, WFIRM

Timothy Leach
PhD Candidate, WFIRM

Shiny Rajan, PhD
PhD Student, WFIRM

Steven Forsythe, PhD
Postdoctoral Student, WFIRM

Oula Khoury
PhD Candidate, WFIRM

RME 2018 Career Perspectives Committee

Kevin Enck
PhD Student, WFIRM

Renata Magalhaes, MD
PhD Student, WFIRM

Peter Prim, PhD
Research Fellow, WFIRM

Andrea Mazzocchi
PhD Candidate, WFIRM

WFIRM Lab Tours

James Yoo, MD, PhD
Assoc. Dir. & CSO, WFIRM

Tracy Criswell, PhD
Assistant Professor, WFIRM

Christopher Porada, PhD
Associate Professor, WFIRM

Sang Jin Lee, PhD
Associate Professor, WFIRM

Young Min Ju, PhD
Instructor, WFIRM

Aleksander Skardal, PhD
Assistant Professor, WFIRM

Colin Bishop, PhD
Professor, WFIRM

Kenneth Gyabaah
Imaging Core Technician, WFIRM

Ray Johnson
Lab Technician, WFIRM

Tara Jones
Genetics Core Technician, WFIRM

Cindy Zimmerman
Histology Core Technician, WFIRM

Other Contributors

Robert Harrison Bardsley IV
Research Lab Technician II, WFIRM

Terri Bowen,
Administrative Manager, WFIRM

Ernie Lookabilll,
Financial Analyst WFIRM

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www.allevi3d.com
Important Information

Registrants may also email Joan Schanck at jschanck@wakehealth.edu to request link be sent to them.

We’re Social!
Like, follow, and connect with the Wake Forest Institute for Regenerative Medicine on social media. Follow along, post pictures, and ask questions by using the hashtag #RMEssentials. We will also post daily pictures from the course on our Facebook account.

@WFIRMnews  @WFIRMnews
Wake Forest Institute for Regenerative Medicine

The RME Course has a mobile application utilizing the Yapp platform. The app contains the agenda, speaker information and much more. Visit http://my.yapp.us/7A58R7 on your mobile device to download.

Internet Access
Connect to IQGuest and accept terms.

Transportation
Complimentary transportation between WFIRM and Bowman Gray Center for Medical Education is provided by ABC Door2Door, adhering to the following schedule:

Monday, June 4th, 12:00 pm to 1:30 pm
From WFIRM (workshops) to Medical Education Center

Wednesday, June 6th, 3:15 pm to 6:00 pm
From Medical Education Center to WFIRM and return as needed

Friday, June 8th, 11:45 am to 1:00 pm
From Medical Education Center to WFIRM

Give your cells a competitive edge
with the most complete xeno-free, serum-free media for transitional research.

- Optimizable media formulations
- Custom scale-up services
- Scientific and regulatory support
- FDA drug master file
- Easily translate to the clinic

Stem Cells Translational Medicine
Submit, search, share, and shape the future

Stem Cells Translational Medicine, the official journal partner of the Regenerative Medicine Foundation, publishes high impact articles and concise reviews related to the clinical translation of all types of stem cells, tissue engineering, and regenerative medicine manufacturing and therapies.

www.StemCellsTM.com
Collagenase NB 6 GMP Grade for Isolation and Passaging of Stem Cells

Collagenase plays a crucial role in isolation and passaging of stem cells dedicated for transplantation into humans. Nordmak Arzneimittel provides Collagenase NB 6 GMP Grade particularly for these clinical applications. This enzyme integrates superior quality with easy handling. It is suitable for isolation of a broad variety of cells, including stem cells (e.g. ADSC), and for stem cell passaging (e.g. hESC).

Collagenase NB 6 GMP Grade is sterile thus it is ready for use. It contains collagenase classes I and II as well as proteolytic activities such as neutral protease and clostripain. Therefore, Collagenase NB 6 GMP Grade is a mild and effective enzyme producing high yields of viable cells.

GMP Compliant Manufacturing
Isolation and passaging of cells dedicated for tissue engineering and transplantation into humans require a collagenase with reliable quality. For this reason Collagenase NB 6 GMP Grade is manufactured in compliance with the EU guide to Good Manufacturing Practice (GMP) for active pharmaceutical ingredient by the German pharmaceutical company Nordmark.

Safety
Collagenase NB 6 GMP Grade meets high safety standards since TSE safety of the manufacturing process is certified by the EDQM. Each lot possesses low endotoxin level and is tested for abnormal toxicity according to European Pharmacopoeia. In addition, data for virus validation and stability studies according to ICH guidelines are available.

Collagenase NB 6 GMP Grade – The superior collagenase for clinical applications

> Outstanding quality – Manufactured in compliance with GMP guidelines
> Ready for use – Sterile according to Ph. Eur.
> Exceptionally safe – Testing of each lot for toxicity
> Reproducibility – Reliable lot-to-lot consistency
> Regulatory advantage – TSE safety certificate & US DMF available

Collagenase NB 6 GMP Grade – Be good to your stem cells so they can be good for you!
Visitor Information

Course Venue: Bowman Gray Center for Medical Education
475 Vine Street
Winston-Salem, NC 27101

From the east (Greensboro): Take I-40W/73N toward Winston-Salem. Following 73N, keep left at the fork to continue on, following signs for I-40W. Merge onto I-40W. Use the right two lanes to take exit 206 for I-40W Business toward Winston-Salem Downtown. Take exit 6C toward ML King Jr. Dr./Winston-Salem State University. Turn right onto ML King Jr. Dr. then left onto E. 4th St. Turn right onto Vine St. then turn right onto E. 7th St. Parking lot P8 will be located on the right past Research Parkway. Follow path down E. 7th St. to turn left onto Vine St. to access the Bowman Gray Center for Medical Education.

From the west (Statesville): Take I-40E to Winston-Salem. Keep left to take exit 188 for I-40E Business toward Winston-Salem/Downtown. Take exit 5D and merge onto Main St. Turn right onto E. 4th St. Turn right onto Vine St. then turn right onto E. 7th St. Parking lot P8 will be located on the right past Research Parkway. Follow path down E. 7th St. to turn left onto Vine St. to access the Bowman Gray Center for Medical Education.

Hotels Near the Bowman Gray Center for Medical Education

- Winston-Salem Marriott
  800-770-5675
- The Kimpton Cardinal Hotel
  336-724-5599
- Marriott Fairfield Inn & Suites
  336-714-2800
- Embassy Suites by Hilton
  336-724-2300
Social Networking and Lab Tours: WFIRM
391 Technology Way
Winston-Salem, NC 27101

From the east (Greensboro):
Take Interstate 40 West. Shortly past the exit for Piedmont Triad International Airport, bear right onto Business 40 West. Cross US Highway 52. Take the first exit (5-D) onto Main Street. Turn right off the exit, and turn right at the next light onto First Street. Cross Church Street. Turn right on Chestnut Street. Take a left on Technology Way. The Richard H. Dean Biomedical Research Building is the last building on the left. The main entrance is between the parking garage and the building, through the outdoor courtyard.

From the west (Statesville): Take Interstate 40 East through Clemmons. Pass Clemmons, bear left onto Business 40 East to Exit 5-D, marked “Old Salem.” Follow the downtown arrow, bearing left on the exit ramp; this will put you on Main Street, headed north. Go to First Street and take a right. Cross Church Street. Turn right on Chestnut Street. Turn left on Technology Way. The Richard H. Dean Biomedical Research Building is the last building on the left. The main entrance is between the parking garage and the building, through the outdoor courtyard.

Social Activities and Receptions
Monday, June 4 - Evening Opening Reception - Bowman Gray
Heavy hors d’oeuvres with beer, wine and soda

Tuesday, June 5 - Afternoon Dips ‘N Sips - Bailey Park
Social networking with appetizers

Wednesday, June 6 - Afternoon Reception - WFIRM
Lab tours and light hors d’oeuvres with beer and wine on the patio

Thursday, June 7 - Southern Dinner Social - Bailey Park
Catered North Carolina BBQ and dessert

Stay an Extra Day: Places to Visit
Old Salem Museums and Gardens
900 Old Salem Rd., Winston-Salem, NC
www.oldsalem.org
In the middle of bustling downtown Winston-Salem, you are steps away from the quieter place of the 18th-century Moravian village of Old Salem Museums and Gardens. Enjoy a self-guided walking tour of the historic town.

Reynolda House Museum of American Art
2250 Reynolda Rd., Winston-Salem, NC
www.reynoldahouse.org

Downtown Arts District & Shopping
400-700 Trade St., Winston-Salem, NC (and surrounding areas)
www.dadaws.org
Downtown/Trade Street District has restaurants, retail shops, residences, business offices, and more located in this eclectic area of downtown between 5th and 7th Streets on Trade Street. Many businesses are housed in historic buildings.

Stay an Extra Day: Places to Eat

The Tavern in Old Salem
736 South Main St.,
336-722-1227

Quanto Basta
680 West 4th St.,
336-893-6144

Sweet Potatoes
529 Trade St.,
336-727-4844

Krankies
211 East 3rd St.,
336-722-3016

Willow’s Bistro
300 South Liberty Ct.,
336-293-460

Famous Toastery
770 Liberty View
336-306-9023

Bib’s Downtown
675 West 5th St.,
336-722-0007

Tavern at Old Salem pecan pie
Quanto Basta roasted chicken
Course Instructors

Anthony Atala, MD  
Director, Wake Forest Institute for Regenerative Medicine

Alphabetical order:

Julie Allickson, PhD  
Director, Regenerative Medicine Clinical Center, Wake Forest Institute for Regenerative Medicine

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

Albert Banes, PhD  
President and Scientific Officer, Flexcell International Corporation; Professor Emeritus, Joint Department of Biomedical Engineering, NCSU and UNC-Chapel Hill

George Christ, PhD  
Professor, Biomedical Engineering and Orthopaedic Surgery; Director of Basic and Translational Research, University of Virginia

Richard Clark, MD  
Professor, Biomedical Engineering and Dermatology, Stony Brook University; Co-Focus Leader, Skin Regeneration, AFIRM II
Delivering on the promise of regenerative medicine requires significant progress in manufacturing to scale up technologies and make them affordable.

Making this progress a reality is the focus of the Regenerative Medicine Development Organization (ReMDO) – a non-profit organization that manages a consortium of more than 60 industry and academic members. The ultimate goal is to accelerate the transition of regenerative medicine technologies to the global market.

Faster Transition of New Therapies to Market

http://ReMDO.org
Bioventus is an orthobiologics company that partners with clinicians and surgeons worldwide to help people resume and enjoy active lives. Its broad portfolio of offerings, engage and enhance the body’s own healing process. Built on a commitment to high quality standards, evidence-based medicine and strong ethical behavior, Bioventus is trusted by physicians and patients.

For more information visit www.Bioventus.com and follow us on Twitter @Bioventusglobal.
Sean Murphy
Assistant Professor, Wake Forest Institute for Regenerative Medicine

Kiran Musunuru, MD, PhD, MPH, FAHA
Associate Professor, University of Pennsylvania

Gail Naughton, PhD
Founder and Chief Scientific Officer, Histogen, Inc.

Christopher Porada, PhD
Associate Professor, Wake Forest Institute for Regenerative Medicine

Adrienne Bell-Cors Shapiro
Founder and Science Administrator, Axis Advocacy Foundation; Ambassador, American for Cures Foundation

Bernard Siegel, JD
Executive Director, Regenerative Medicine Foundation

Aleksander Skardal, PhD
Assistant Professor, Wake Forest Institute for Regenerative Medicine

Julie Watson, JD
Special Counsel, Marshall, Gerstein & Borun, LLP; Intellectual Property Director and Legal Counsel, WFIRM

Nick Willett, PhD
Assistant Professor, Orthopaedics, Emory University

David Williams, DSc
Professor and Director of International Affairs, WFIRM

James J. Yoo, MD, PhD
Associate Director and Chief Scientific Officer, WFIRM
### Agenda

#### Day 1: Monday, June 4th

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<th>Time</th>
<th>Session</th>
<th>Location</th>
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<tr>
<td>11:45am - 1:15pm</td>
<td>Arrival and Registration</td>
<td>5th Floor</td>
</tr>
<tr>
<td>1:15pm - 1:30pm</td>
<td>Welcome and Opening Remarks</td>
<td>5107</td>
</tr>
<tr>
<td>1:30pm - 2:15pm</td>
<td><strong>Introduction and Background: Current Concepts and Changing Trends</strong></td>
<td>5107</td>
</tr>
<tr>
<td>2:15pm - 3:00pm</td>
<td>Stem Cells, Basic Biology, Therapeutics, and Vehicles for Gene Delivery</td>
<td>5107</td>
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<tr>
<td>3:00pm - 3:15pm</td>
<td>Coffee Break</td>
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<tr>
<td>3:15pm - 4:00pm</td>
<td>Stem Cell-Derived Retinal Pigmented Epithelium: Translation of a Cellular Therapy for Age-Related Macular Degeneration</td>
<td>5107</td>
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<tr>
<td>4:00pm - 4:30pm</td>
<td>Panel and Attendees Discussion</td>
<td>5107</td>
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<tr>
<td>4:30pm - 6:00pm</td>
<td>Brief Closing Remarks</td>
<td>5107</td>
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#### Day 2: Tuesday, June 5th

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<tr>
<th>Time</th>
<th>Session</th>
<th>Location</th>
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<tbody>
<tr>
<td>7:45am - 8:30am</td>
<td>Networking and Continental Breakfast</td>
<td>5th Floor</td>
</tr>
<tr>
<td>8:30am - 9:10am</td>
<td>Essential Biomaterials Science</td>
<td>5107</td>
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<tr>
<td>9:10am - 9:50am</td>
<td>Engineering Naturally Derived Hydrogels for Applications in Regenerative Medicine</td>
<td>5107</td>
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<tr>
<td>9:50am - 10:10am</td>
<td>Coffee Break and Exhibits</td>
<td>5th Floor</td>
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<tr>
<td>10:10am - 10:50am</td>
<td>Engineering and Applications of Biomaterials in 3D Printing</td>
<td>5107</td>
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#### Session 2: Biomaterials

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<th>Time</th>
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<tbody>
<tr>
<td>10:50am - 11:30am</td>
<td>Synthetic Biomaterials for Engineering Bone and Cartilage Implants</td>
<td>5107</td>
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<tr>
<td>11:30am - 12:00pm</td>
<td>Panel and Attendees Discussion</td>
<td>5107</td>
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<tr>
<td>12:00pm - 1:15pm</td>
<td>Lunch Break and Exhibits</td>
<td>Room TBC</td>
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<tr>
<td>12:00pm - 1:15pm</td>
<td>Career Perspectives in Academia: How to Prepare Yourself for an Academic Career</td>
<td>Room TBC</td>
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#### Session 3: Enabling Technologies

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Location</th>
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<tbody>
<tr>
<td>1:15 pm – 2:00 pm</td>
<td>Overview of Enabling Technologies in Regenerative Medicine (w/ Gene Therapy Applications)</td>
<td>5107</td>
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<tr>
<td>2:00 pm – 2:45 pm</td>
<td>Tracking Stem Cells Anywhere in the Body - A Look at Regenerative Imaging</td>
<td>5107</td>
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<tr>
<td>2:45 pm – 3:00 pm</td>
<td>Coffee Break and Exhibits</td>
<td>5th Floor</td>
</tr>
<tr>
<td>3:00 pm - 3:45 pm</td>
<td>Bioprinting: Enabling Technology for Tissue Engineering and Regenerative Medicine</td>
<td>5107</td>
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<tr>
<td>3:45 pm - 4:30 pm</td>
<td>Genome Editing for Research and Therapeutic Applications</td>
<td>5107</td>
</tr>
<tr>
<td>4:30 pm – 4:45 pm</td>
<td>Flexcell’s Dynamic 2 and 3D culture Systems for Stem Cell Tissue engineering</td>
<td>5107</td>
</tr>
<tr>
<td>4:45 pm - 5:00 pm</td>
<td>Panel and Attendees Discussion</td>
<td>5th Floor</td>
</tr>
<tr>
<td>5:00 pm – 6:00 pm</td>
<td>Refreshments and Networking</td>
<td>5th Floor</td>
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#### Day 3: Wednesday, June 6th

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Location</th>
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<tbody>
<tr>
<td>8:00am - 8:45am</td>
<td>Networking and Continental Breakfast</td>
<td>5th Floor</td>
</tr>
<tr>
<td>8:45am - 9:30am</td>
<td>Overview w/Applications of Perinatal Stem Cells</td>
<td>5107</td>
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#### Session 4: Cell Therapies

<table>
<thead>
<tr>
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<tr>
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<td>Bioprinting: Enabling Technology for Tissue Engineering and Regenerative Medicine</td>
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<tr>
<td>3:45 pm - 4:30 pm</td>
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<tr>
<td>4:30 pm – 4:45 pm</td>
<td>Flexcell’s Dynamic 2 and 3D culture Systems for Stem Cell Tissue engineering</td>
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<tr>
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<td>Panel and Attendees Discussion</td>
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<tr>
<td>5:00 pm – 6:00 pm</td>
<td>Refreshments and Networking</td>
<td>5th Floor</td>
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**Session 5: Tissue Engineered Products & Technologies (TEMPs)**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event DESCRIPTION</th>
<th>Speaker(s)</th>
<th>Location</th>
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</thead>
<tbody>
<tr>
<td>1:30pm - 2:10pm</td>
<td>Considerations for Developing Tissue Engineered and Regenerative Medicine Products</td>
<td>James Yoo, MD, PhD (Chair)</td>
<td>5107</td>
</tr>
<tr>
<td>2:10pm - 2:50pm</td>
<td>Translational Effort: Bringing a Regenerative Medicine Product to Patients</td>
<td>Saverio La Francesca, MD, Founder and CEO Orgagen, Inc.</td>
<td>5107</td>
</tr>
<tr>
<td>2:50pm - 3:10pm</td>
<td>Coffee Break and Exhibits</td>
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<td>5th Floor</td>
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<tr>
<td>3:10pm - 3:50pm</td>
<td>Regenerative Skin Substitutes: Discovery to Phase III Trial in Burns</td>
<td>Allen Comer, PhD, Director of R&amp;D, Stratatech</td>
<td>5107</td>
</tr>
<tr>
<td>3:50pm - 4:20pm</td>
<td>Panel and Attendees Discussion</td>
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<tr>
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<td>Coffee Break and Exhibits</td>
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<td>5th Floor</td>
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<tr>
<td>4:30pm - 5:45pm</td>
<td>WFIRM &quot;Into the Lab&quot; Tours (Shuttle Service or Walk. Van shuttle to WFIRM from WF Medical Education Center from 3:15 pm to 5:45 pm). Social Networking at WFIRM with Refreshments (Light Hors D’oeuvres and Beer/Wine)</td>
<td>WFIRM</td>
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**Day 4: Thursday, June 7th**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
<th>Location</th>
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<tbody>
<tr>
<td>9:30am - 10:45am</td>
<td>Stem Cell Therapies for Human Heart Disease</td>
<td>5107</td>
</tr>
<tr>
<td>10:45am - 11:05am</td>
<td>Coffee Break and Exhibits</td>
<td>5th Floor</td>
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<tr>
<td>11:05am - 11:50am</td>
<td>Game Changers: Using Cord Blood to Help the Brain</td>
<td>5107</td>
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<tr>
<td>11:50am - 12:20pm</td>
<td>Panel and Attendees Discussion</td>
<td>5107</td>
</tr>
<tr>
<td>12:20pm - 1:30pm</td>
<td>Lunch Break and Exhibiting</td>
<td>5th Floor</td>
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**Session 6: Regulatory, Process Development & Manufacturing**

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<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
<th>Speaker(s)</th>
<th>Location</th>
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</thead>
<tbody>
<tr>
<td>8:30am - 8:45am</td>
<td>Presenting Sponsor: Nordmark Biochemicals Collagenase: The Key Enzyme in the Process of Cell Isolation</td>
<td>Johanna Moench, PhD, Head of Nordmark Biochemicals</td>
<td>5107</td>
</tr>
<tr>
<td>8:45am - 9:15am</td>
<td>Intro to translation in Academia: Challenges and Possible solutions</td>
<td>Julie Allickson, PhD, WFIRM (Chair)</td>
<td>5107</td>
</tr>
<tr>
<td>9:15am - 9:50am</td>
<td>Evolution of the Regulatory Framework for Regenerative Medicine</td>
<td>Peter Marks, PhD, Director, CBER, FDA</td>
<td>5107</td>
</tr>
<tr>
<td>9:50am - 10:05am</td>
<td>Coffee Break and Exhibits</td>
<td></td>
<td>5th Floor</td>
</tr>
<tr>
<td>10:05am - 10:40am</td>
<td>Topics Covered: How Federal Funding Agencies Interdigitate w/FDA, 21st Century Cures Act, New RM Biofab (Title TBC)</td>
<td>Martha Lundberg, PhD, NIH</td>
<td>5107</td>
</tr>
<tr>
<td>10:40am - 11:15am</td>
<td>Advocacy and the 21st Century Cures Act (Title TBC)</td>
<td>Robert Klein, President and Founder, Americans for Cures</td>
<td>5107</td>
</tr>
<tr>
<td>11:15am - 11:45am</td>
<td>Panel and Attendees Discussion</td>
<td></td>
<td>5107</td>
</tr>
<tr>
<td>11:45am - 12:45pm</td>
<td>Lunch Break and Exhibiting</td>
<td></td>
<td>5th Floor</td>
</tr>
<tr>
<td>11:45am - 12:45pm</td>
<td>Student Mentor Luncheon Session II Careers in Industry Panel</td>
<td>PhD Candidates: Kevin Enck and Andrea Mazzocchi</td>
<td>Room TBC</td>
</tr>
</tbody>
</table>

**Session 7: Clinical Trials & Bioethics**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
<th>Speaker(s)</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:45pm - 1:25pm</td>
<td>IND/IDE: The Good, the Bad and the UGLY!</td>
<td>Richard Clark, PhD, Stony Brook Foundation</td>
<td>5107</td>
</tr>
</tbody>
</table>
Day 5: Friday, June 8th

8:00 am - 8:45 am
Continental Breakfast

**Session 9: Commercialization**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter/Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:45 am - 9:25 am</td>
<td>IP 101: Securing IP for Regenerative Medicine Technologies</td>
<td>Julie Watson, JD, WFIRM</td>
</tr>
<tr>
<td>9:25 am - 10:00 am</td>
<td>Opportunities and Risks for Commercializing Novel RM Technologies</td>
<td>Julie Watson, JD, WFIRM</td>
</tr>
<tr>
<td>10:00 am - 10:20 am</td>
<td>Coffee Break</td>
<td></td>
</tr>
<tr>
<td>10:20 am - 11:00 am</td>
<td>TBC - Commercialization in Action</td>
<td>Gail Naughton, PhD, Histogen</td>
</tr>
<tr>
<td>11:00 am - 11:45 am</td>
<td>Patient Perspectives w/Americans for Cures Pt. Advocate (Title TBC)</td>
<td>Adrienne Bell-Cors Shapiro, Patient Advocate, w/Bernard Siegel, JD, RMF (Moderator)</td>
</tr>
<tr>
<td>11:45 am - 12:00 pm</td>
<td>Wrap-Up and Concluding Remarks</td>
<td>Joan Schanck, MPA, WFIRM</td>
</tr>
</tbody>
</table>

**Day 4: Thursday, June 7th**

7:45am - 8:30 am
Networking and Continental Breakfast

**Session 6: Regulatory, Process Development & Manufacturing**

**Presenting Sponsor: Nordmark Biochemicals**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter/Location</th>
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</thead>
<tbody>
<tr>
<td>8:45 am - 9:15 am</td>
<td>Collagenase: The Key Enzyme in the Process of Cell Isolation</td>
<td>Johanna Moench, PhD, NIH</td>
</tr>
<tr>
<td>9:15 am - 10:05 am</td>
<td>Coffee Break and Exhibits</td>
<td></td>
</tr>
<tr>
<td>10:05 am - 10:40 am</td>
<td>Advocacy and the 21st Century Cures Act  (Title TBC)</td>
<td>Martha Lundberg, PhD, NIH</td>
</tr>
<tr>
<td>11:15am - 11:45am</td>
<td>Panel and Attendees Discussion</td>
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</tr>
<tr>
<td>11:45 am - 12:45 pm</td>
<td>Lunch Break and Exhibiting</td>
<td></td>
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</tbody>
</table>

**Day 3: Wednesday, June 6th (cont.)**

2:05 pm - 2:20 pm
Focus Break with Synapse and Exhibits