

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

Official Course of



REGENERATIVE
MEDICINE
FOUNDATION



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

Welcome to Regenerative Medicine Essentials 2018

On behalf of the Regenerative Medicine Foundation (RMF), I welcome you to RMF's "official course"—the 5th annual *Regenerative Medicine Essentials: From the Fundamentals to the Future*. We believe the course is a perfect platform for advancing the RMF mission to accelerate regenerative medicine to improve health and deliver cures.

Here at RMF, we recognize that the power of collaboration grows in a nonlinear fashion. One plus one is more than two, and one plus one plus one is much, much more than three — offering explosively positive and unpredictable possibilities. By attending this course, you will expand your knowledge in a totally immersive experience and gain personal connections and collaborations. Be open to all opportunities presented.

Interact with the outstanding interdisciplinary faculty and the superlative researchers of our host institution, the Wake Forest Institute for Regenerative Medicine, led by our treasured friend, Dr. Anthony Atala. We are here for you. Open to your questions and points of view.

This week I urge you to network with fellow attendees. Break bread, make new friends and remember to collect those opportunities.

In my journey, I have found Winston-Salem to be one of the most collegial places on the planet. This week, I assure you, it's the best place to learn about the future of medicine!

Cordially,

Bernard Siegel, JD
Executive Director, Regenerative Medicine Foundation
Founder & Chair, World Stem Cell Summit



**REGENERATIVE
MEDICINE**
FOUNDATION

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
Assit. 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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Important Information

RME 2018 Course Materials Dropbox link: <http://bit.ly/RME18>

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.



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

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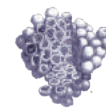
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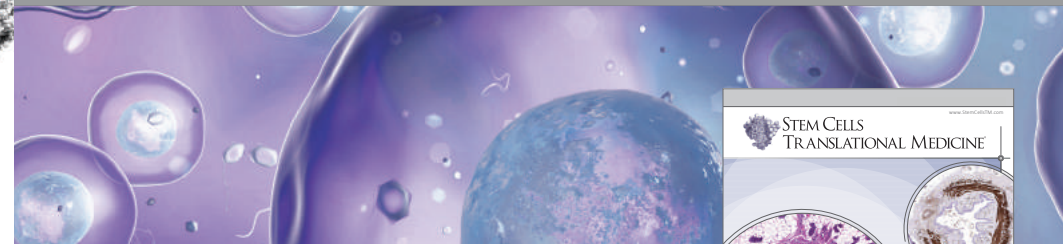
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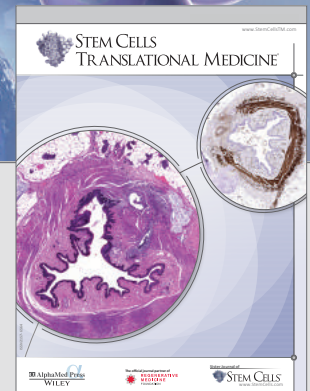


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Technical Notes

Collagenase NB 6 GMP Grade For Isolation and Passaging of Stem Cells

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.

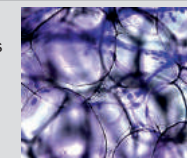


Safety

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



Human adipose tissue, by courtesy of Pharmicell Europe GmbH, Germany

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.



Bowman Gray Center for Medical Education

Bowman Gray Center for Medical Education FIFTH FLOOR



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.



Wake Forest Institute for Regenerative Medicine

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

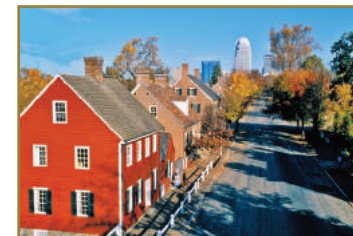
Thursday, June 7 - Southern Dinner Social - Bailey Park
Catered North Carolina BBQ and dessert

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.



Old Salem

Reynolda House Museum of American Art

2250 Reynolda Rd., Winston-Salem, NC
www.reynoldahouse.org

The Reynolda House Museum of American Art holds a stellar collection of American art, decorative arts and costumes that transport visitors into the era of the early 20th century. Nearby Reynolda Village offers shops and restaurants.

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

Sweet Potatoes

529 Trade St.,
336-727-4844

Willow's Bistro

300 South Liberty Ct.,
336-293-460

Bib's Downtown

675 West 5th St.,
336-722-0007

Quanto Basta

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

Krankies

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

Famous Toastery

770 Liberty View
336-306-9023



Tavern at Old Salem pecan pie



Quanto Basta roasted chicken

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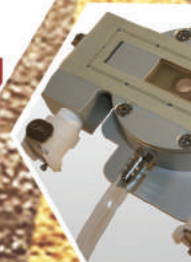
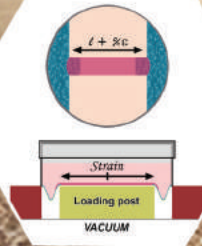
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Course Instructors



Anthony Atala, MD

Director, Wake Forest Institute for Regenerative Medicine



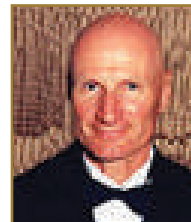
Julie Allickson, PhD

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





Dennis Clegg, PhD

Co-Director, UC Santa Barbara Center for Stem Cell Biology and Engineering



Allen Comer, PhD

Director, Research and Development, Regenerative Medicine, Stratatech, a Mallinckrodt Company



John Fisher, PhD

Professor and Department Chair, University of Maryland; Director, NIH Center for Engineering Complex Tissues



Joshua Hare, MD, FACC, FAHA

Founding Director, Interdisciplinary Stem Cell Institute; Professor of Medicine, University of Miami



Nancy King, JD

Co-Director, Center for Bioethics, Health and Society, Wake Forest University



Robert Klein, JD

Chairman and President, Klein Financial Corporation; Chairman, Americans for Cures; Chairman Emeritus, California Institute for Regenerative Medicine (CIRM)



Joanne Kurtzberg, MD

Director, Pediatric Blood and Marrow Transplant Program; Chief Scientific and Medical Officer, Robertson Clinical and Translational Cell Therapy Program, Duke Medical Center



Saverio La Francesca, MD

Founder and CEO, Orgagen, Inc.



Martha Lundberg, PhD

Program Director, Advanced Technologies and Surgery Branch, National Heart, Lung, and Blood Institute (NHLBI)

Faster Transition of New Therapies to Market



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.



<http://ReMDO.org>



Frank Marini, PhD

Professor, Wake Forest Institute for Regenerative Medicine



Peter Marks, MD, PhD

Director, Center for Biologics Evaluation and Research



Todd McAllister, PhD

Executive Director, Amnion Foundation



Anthony J. Melchiorri, PhD

Associate Director, Biomaterials Lab at Rice University; Assistant Director, Center for Engineering Complex Tissues



Michel Modo, PhD

Professor, Departments of Radiology & Bioengineering, McGowan Institute for Regenerative Medicine; Center for Neural Basis Cognition, University of Pittsburgh



Johanna Mönch, PhD

Head of Nordmark Biochemicals Division, Nordmark Arzneimittel GmbH & Co. KG

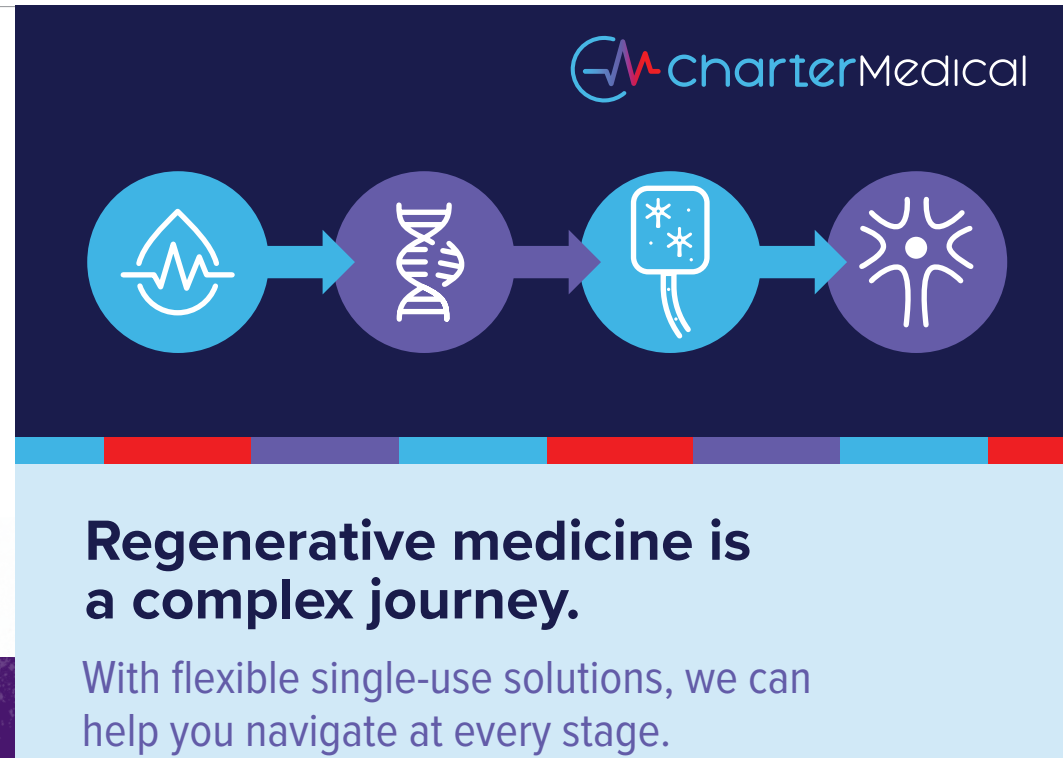


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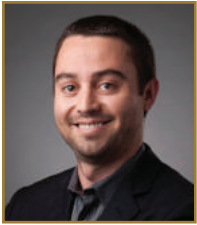
For more information visit www.Bioventus.com
and follow us on Twitter [@Bioventusglobal](https://twitter.com/Bioventusglobal).



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Regenerative medicine is a complex journey.

With flexible single-use solutions, we can help you navigate at every stage.



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



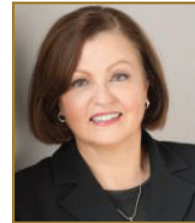
Bernard Siegel, JD

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

11:45am - 1:15pm 1:15pm - 1:30pm	Arrival and Registration Welcome and Opening Remarks	Joan Schanck MPA, WFIRM	5th Floor 5107
Session 1: Pluripotent Stem Cells and their Progenitors			
1:30pm - 2:15pm	<i>Introduction and Background: Current Concepts and Changing Trends</i>	Anthony Atala, MD, Director, WFIRM	5107
2:15pm - 3:00pm	<i>Stem Cells, Basic Biology, Therapeutics, and Vehicles for Gene Delivery</i>	Graça Almeida-Porada, MD, PhD, WFIRM (Chair)	5107
3:00pm - 3:15pm	Coffee Break		5th Floor 5107
3:15pm - 4:00pm	<i>Stem Cell-Derived Retinal Pigmented Epithelium: Translation of a Cellular Therapy for Age-Related Macular Degeneration</i>	Dennis Clegg, PhD, UC Santa Barbara	5107
4:00pm - 4:30pm	Panel and Attendees Discussion Brief Closing Remarks		First Floor/ Outdoor Patio
4:30pm - 6:00pm	(Heavy Hors D'oeuvres and Beer/Wine)		

Day 2: Tuesday, June 5th

7:45am - 8:30am	Networking and Continental Breakfast		5th Floor
Session 2: Biomaterials			
8:30am - 9:10am	<i>Essential Biomaterials Science</i>	David Williams, PhD, WFIRM (Chair)	5107
9:10am - 9:50am	<i>Engineering Naturally Derived Hydrogels for Applications in Regenerative Medicine</i>	Aleks Skardal, PhD, WFIRM	5107
9:50am - 10:10am	Coffee Break and Exhibits		5th Floor
10:10am - 10:50am	<i>Engineering and Applications of Biomaterials in 3D Printing</i>	John Fisher, PhD, U of Maryland	5107

10:50am - 11:30am	<i>Synthetic Biomaterials for Engineering Bone and Cartilage Implants</i>	Anthony Melchiorri, PhD, Rice University	5107
11:30am - 12:00pm 12:00pm - 1:15 pm	Panel and Attendees Discussion Lunch Break and Exhibits		5107 5th Floor
12:00pm - 1:15 pm	Student-Mentor Luncheon Session I <i>Career Perspectives in Academia: How to Prepare Yourself for an Academic Career</i>	Peter Prim, PhD, Postdoctoral Fellow and Renata Magalhaed, MD, Pre-doctoral Fellow	Room TBC

Session 3: Enabling Technologies



1:15 pm – 2:00 pm	<i>Overview of Enabling Technologies in Regenerative Medicine (w/ Gene Therapy Applications)</i>	Christopher Porada, PhD, WFIRM (Chair)	5107
2:00 pm – 2:45 pm	<i>Tracking Stem Cells Anywhere in the Body - A Look at Regenerative Imaging</i>	Frank Marini, PhD, WFIRM	5107
2:45 pm – 3:00 pm	Coffee Break and Exhibits		5th Floor 5107
3:00 pm - 3:45 pm	<i>Bioprinting: Enabling Technology for Tissue Engineering and Regenerative Medicine</i>	John Jackson, PhD, WFIRM	
3:45 pm - 4:30 pm	<i>Genome Editing for Research and Therapeutic Applications</i>	Kiran Musunuru, MD, MPH, FAHA, U of Pennsylvania	5107
4:30 pm – 4:45 pm	<i>Flexcell's Dynamic 2 and 3D culture Systems for Stem Cell Tissue engineering</i>	Albert J. Banes, PhD, President, Flexcell	5107
4:45 pm - 5:00 pm 5:00 pm – 6:00 pm	Panel and Attendees Discussion Refreshments and Networking		5107 5th Floor

Day 3: Wednesday, June 6th

8:00am - 8:45am	Networking and Continental Breakfast		5th Floor
Session 4: Cell Therapies			
8:45am - 9:30am	<i>Overview w/Applications of Perinatal Stem Cells</i>	Sean Murphy, PhD, WFIRM (Chair)	5107

9:30am-10:45am	<i>Stem Cell Therapies for Human Heart Disease</i> Coffee Break and Exhibits	Joshua Hare, MD, U of Miami	5107
10:45am - 11:05am			5th Floor
11:05am - 11:50 am		Joanne Kurtzberg, MD, Duke Medical Center	5107
11:50am - 12:20pm	Panel and Attendees Discussion		5107
12:20pm - 1:30 pm	Lunch Break and Exhibiting		5th Floor
Session 5: Tissue Engineered Products & Technologies (TEMPS)			
1:30pm - 2:10pm	<i>Considerations for Developing Tissue Engineered and Regenerative Medicine Products</i>	James Yoo, MD, PhD (Chair)	5107
2:10pm - 2:50pm	<i>Translational Effort: Bringing a Regenerative Medicine Product to Patients</i>	Saverio La Francesca, MD, Founder and CEO Orgagen, Inc.	5107
2:50pm - 3:10 pm	Coffee Break and Exhibits		5th Floor
3:10pm-3:50pm	<i>Regenerative Skin Substitutes: Discovery to Phase III Trial in Burns</i>	Allen Comer, PhD, Director of R&D, Stratatech	5107
3:50pm- 4:20 pm	Panel and Attendees Discussion		5107
4:20pm - 5:00pm	Coffee Break and Exhibits		5th Floor
4:30pm - 5:45pm	WFIRM "Into the Lab" Tours (Shuttle Service or Walk. Van shuttle to WFIRM from WF Medical Education Center from 3:15 pm to 5:45 pm).		WFIRM
4:30pm - 6:00 pm	Social Networking at WFIRM with Refreshments (Light Hors D'oeuvres and Beer/Wine)		WFIRM
Day 4: Thursday, June 7th			
7:45am - 8:30 am	Networking and Continental Breakfast		5th Floor

Session 6: Regulatory, Process Development & Manufacturing			
8:30 am - 8:45 am	<i>Presenting Sponsor: Nordmark Biochemicals</i> <i>Collagenase: The Key Enzyme in the Process of Cell Isolation</i>	Johanna Moench, PhD, Head of Nordmark Biochemicals	5107
8:45 am - 9:15 am	<i>Intro to translation in Academia: Challenges and Possible solutions</i>	Julie Allickson, PhD, WFIRM (Chair)	5107
9:15 am - 9:50 am	<i>Evolution of the Regulatory Framework for Regenerative Medicine</i>	Peter Marks, PhD, Director, CBER, FDA	5107
9:50 am - 10:05 am	Coffee Break and Exhibits		5th Floor
10:05 am - 10:40 am	<i>Topics Covered: How Federal Funding Agencies Interdigitate w/FDA, 21st Century Cures Act, New RM Biofab (Title TBC)</i>	Martha Lundberg, PhD, NIH	5107
10:40 am - 11:15 am	<i>Advocacy and the 21st Century Cures Act (Title TBC)</i>	Robert Klein, President and Founder, Americans for Cures	5107
11:15am - 11:45am	Panel and Attendees Discussion		5107
11:45 am - 12:45 PM	Lunch Break and Exhibiting		5th Floor
11:45 am 12:45 pm	Student Mentor Luncheon Session II <i>Careers in Industry Panel</i>	PhD Candidates: Kevin Enck and Andrea Mazzocchi	Room TBC
Session 7: Clinical Trials & Bioethics			
12:45pm - 1:25 pm	<i>IND/IDE: The Good, the Bad and the UGLY!</i>	Richard Clark, PhD, Stony Brook Foundation	5107

1:25pm - 2:05 pm	<i>Clinical Trials Case Studies: Commercial and Ethical Considerations for Execution and Reporting of Clinical Trials</i>	Todd McAllister, PhD, Amnion	5107
2:05 pm - 2:20 pm	Focus Break with Synapse and Exhibits		5th Floor
2:20 pm - 2:50 pm	<i>Translation Regenerative Medicine Research: Ethics Overview</i>	Nancy King, JD, Wake Forest	5107
2:50 pm - 3:10 pm	Panel and Attendees Discussion		5107
3:10 - 3:30 pm	Coffee Break and Exhibits		5th Floor
Session 8: Regenerative Rehabilitation			
3:30 pm - 4:05 pm	<i>Principles of Regenerative Rehabilitation</i>	Nick Willett, PhD, Emory	5107
4:05 pm - 4:40 pm	<i>Interactive Effects of Rehabilitation and Cell Therapy to Treat Brain Damage</i>	Michel Modo, PhD, University of Pittsburgh	5107
4:40 pm - 5:15pm	<i>Musculoskeletal Regenerative Rehabilitation</i>	George Christ, PhD, University of Virginia	5107
5:15 pm - 5:30 pm	Panel and Attendees Discussion		5107
5:30pm - 6:45pm	NC BBQ ft. Sonny's BBQ and Social Networking		Bailey Park

Day 5: Friday, June 8th			
8:00 am - 8:45 am	Continental Breakfast		5th Floor
Session 9: Commercialization			
	Session Moderator	Bernard Siegel, JD, RMF (Moderator)	5107
8:45 am - 9:25 am	<i>IP 101: Securing IP for Regenerative Medicine</i>	Julie Watson, JD, WFIRM	5107
9:25 am - 10:00 am	<i>Opportunities and Risks for Commercializing Novel RM Technologies</i>	Julie Watson, JD, WFIRM	5107
10:00 am - 10:20 am	Coffee Break		5th Floor
10:20 am - 11:00 am	<i>TBC - Commercialization in Action</i>	Gail Naughton, PhD, Histogen	5107
11:00 am - 11:45am	<i>Patient Perspectives w/Americans for Cures Pt. Advocate (Title TBC)</i>	Adrienne Bell-Cors Shapiro, Patient Advocate, w/Bernard Siegel, JD, RMF (Moderator)	5107
11:45 am - 12:00 pm	Wrap-Up and Concluding Remarks	Joan Schanck, MPA, WFIRM	5107