

Regenerative Medicine Essentials: The Fundamentals to the Future

July 11-15, 2016
Winston-Salem, NC
wakehealth.edu/RMEssentials

Regenerative Medicine Essentials Course 2016

Pre- and Post- Into the Lab Workshops - Monday, July 11th and Friday, July 15th, 2016

(Workshops run concurrently)



Workshop #1: Perfusion
Decellularization and
Recellularization of Whole Organs
Workshop Director: Thomas Shupe,
PhD, WFIRM



Workshop #2: From Concept to Clinic:
Introduction to Translation in Regenerative
Medicine (cGMP/GTP Cell Process, etc.)
Workshop Director: Julie Allickson, PhD,
WFIRM



Workshop #3: Bioprinting Basics for
Regenerative Medicine
Workshop Director: John Jackson, PhD,
WFIRM with BioBots

Overview: We are excited to offer three new Into the Lab workshops. These workshops will be held at the Wake Forest Institute for Regenerative Medicine (WFIRM) on **July 11th (9:00am - 12:15pm) and/or July 15th (1:30pm - 4:45pm)**. Each will 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.

Workshops Location: These workshops are held at the Wake Forest Institute for Regenerative Medicine (WFIRM), located in the Richard H. Dean Building, 391 Technology Way, Winston-Salem, NC.

Registration: Pre-workshop registration will be held on July 11th, 2016 and will take place at WFIRM on the second floor, collaboration area. There will be signs and personnel to direct you. Please plan to arrive by 8:15 am. Post-workshop, registration will be held on July 15th and will also take place at WFIRM. The post-workshops will begin promptly at 1:30 pm.

Shuttle Service: The workshop and RME course site are within walking distance; however, shuttle service will be provided. You will be directed to shuttle point. Map also attached.

Special Considerations: Please note that cameras/photos are not permitted during the workshops.

RM Essentials 2016 - *Into the Lab* Workshops Agendas:

July 11th, 2016: Pre-Workshops Schedule In Brief

(See detailed pre-workshop schedules attached)

- 8:00 am to 8:15 am Workshop Participants arrive at Wake Forest Institute for Regenerative Medicine (WFIRM).
- 8:15 am to 8:45 am Registration/Coffee Service, 2nd Floor, Collaboration area
- 8:45 am to 9:00 am Welcome/Overview (Schanck)
- 9:00 am to 12:15 pm Break into Workshop Groups - ***Refer to De-cell, Translation, and Bioprinting Workshop Agendas*** (Workshops run concurrently, including coffee break)
- 12:15 pm to 12:40 pm Lunch w/workshop instructors (Room 250 A&B)
- 12:40 pm to 1:00 pm Shuttle to Biotech Place for RME Course Opening (5 min. drive)



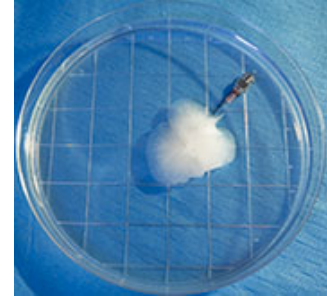
July 15th, 2016: Post-Workshops Schedule In Brief

(See detailed post-workshops schedules attached)

- 12:15 pm RME Course at Biotech Place concludes
- 12:15 pm to 1:00 pm Lunch on your own (Option at Biotech Place and within walking distance)
- 1:00 pm to 1:15 pm Shuttle service to Wake Forest Institute for Regenerative Medicine
- 1:15 pm to 1:30 pm Registration-Check in
- 1:30 pm to 4:45 pm Break into Workshop Groups - ***Refer to De-cell, Translation, and Bioprinting Workshop Agendas*** (Workshops run concurrently, including coffee break)
- 4:45 pm Wrap-up/Departure

Workshop #1: Perfusion Decellularization

- Pre-Workshops held Monday, July 11, 2016 (9 am to 12:15 pm)
- Post-Workshops held Friday, July 15, 2016 (1:30 pm to 4:45 pm)



PRE- DECELL WORKSHOP -- Monday, July 11th -- Morning Schedule (Registration at 8:15 am. Workshop from 9 am to 12:15 pm)

9:00 am to 9:10 am	Introduction – Aleks Skardal (Room 439) – (10 min)
9:15 am to 9:35 am	Mechanical Characteristics – Hesh Devarasetty (4 th Floor) (20 min)
9:35 am to 10:05 am	Small scale decell demonstration - Cindy Zimmerman (4 th floor lab east) (30 min)
10:10 am to 10:30 am	Large scale decell demonstration - In Kap Ko (2 nd floor lab west) (20 min)
10:30 am to 10:50 am	Vessel casting - J.P. Zambon (2 nd floor lab west) (20 min)
10:50 am to 11:00 am	Break (2 nd floor collaboration area) (10 min)
11:00 am to 11:20 am	Small tissue processing - Young Min Ju and John Jackson (4 th floor lab west) (20 min)
11:20 am to 11:45 am	Processing for incorporation into hydrogels – Julio Aleman and Kevin Enck (4 th floor lab west) (25 min)
11:45 am to 12:00 pm	Processing of intact tissue for cell culture – Matthew Brovold and Abritee Dhal (3 rd floor Histology) (15 min)
12:00 pm to 12:10 pm	Closing remarks/Q&A - Aleks Skardal (Room 439) - (10 Min)
12:00/12:10 pm to 12:40 pm	Box lunch with workshops (Room 250 A&B)
12:40 pm to 1:00 pm	Shuttle to Biotech Place for RME Course Opening

Workshop #1: Perfusion Decellularization

POST DECELL WORKSHOP -- Friday, July 15th – Afternoon Schedule

(Shuttle from Biotech Place to WFIRM at 1:00-1:15pm, Workshops from 1:30 pm to 4:45 pm)

1:30 pm to 1:40 pm	Introduction – Aleks Skardal (Room 250A) (10 min)
1:40 pm to 2:00 pm	Mechanical Characteristics – Hesh Devarasetty (4 th Floor) (20 min)
2:05 pm to 2:35 pm	Small scale decell demonstration - Cindy Zimmerman (4 th floor lab east) (30 min)
2:40 pm to 3:00 pm	Large scale decell demonstration - In Kap Ko (2 nd floor lab west) (20-25 min)
3:00 pm to 3:20 pm	Vessel casting - J.P. Zambon (2 nd floor lab west) (20 min)
3:20 pm to 3:30 pm	Break (2 nd floor collaboration area) (10 min)
3:30 pm to 3:50 pm	Small tissue processing - Young Min Ju and John Jackson (4 th floor lab west) (20 min)
3:50 pm to 4:15 pm	Processing for incorporation into hydrogels – Julio Aleman and Kevin Enck (4 th floor lab west) (25 min)
4:15 pm to 4:30 pm	Processing of intact tissue for cell culture – Matthew Brovold and Arbitee Dhal (3 rd floor Histology) (15 min)
4:30 pm to 4:40 pm	Closing remarks/Q&A - Aleks Skardal (10 Min) – (Room 250A)

Workshop #2: From Concept to Clinic: Introduction to Translation in RM

- Pre-Workshop held Monday, July 11, 2016 (9 am to 12:15 pm)



PRE- TRANSLATION WORKSHOP -- Monday, July 11th – Morning Schedule

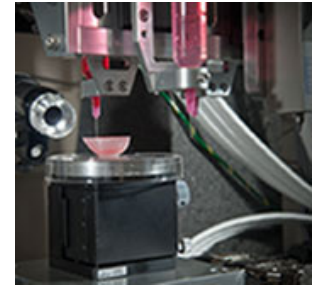
9:00 am to 9:10 am	Translation Overview – Julie Allickson (<i>10 Min</i>) (Room 250 A) <ul style="list-style-type: none">• Introduction• Definition of Translation• Intro to Schedule for the Workshop
9:10 am to 10:10 am	Process Development – Rich Payne (<i>60 Min</i>) <ul style="list-style-type: none">• Introduction• Define / describe patient defect in need of repair (unmet medical need)• Define / describe organ / tissue to be used as case study throughout• Define key terms (scaffold, construct, cell culture, etc.)• Flow chart of process• SOPs• FDA meeting conference call• IND filing• Carry through mock process development steps with hands-on where possible
10:15 am to 10:20 am	Project Management
10:20 am to 11:10 am	Manufacturing- Darren Hickerson (<i>50 Min</i>) <ul style="list-style-type: none">• Overview / intro<ul style="list-style-type: none">○ Define clean room and purpose, structure (HEPA, layout, etc.) to achieve defined purpose○ ISO classifications, etc. (handout), Define GMP○ Proper movements in hood and in clean room, door lights, unidirectional movement (personnel and materials), etc.• Gowning (hands on)• Pass materials into the clean room / hood etc.• Documentation: Batch records, etc. (how developed, why used, hands on activity)• Isolate key cells and plate (hands-on activity)

Pre-Workshop #2, July 11th, 2016 (cont.)

- 11:10 am to 11:50 pm Quality Systems- Todd Meinecke (*50 Min*)
- Overview / intro
 - Define QC / QA
 - Key FDA regs, etc.
 - Define 351 / 361, etc.
 - Discuss validation, qualification, etc. (unless covered in PD?)
 - Perform a document review
 - Write up deviation
 - Perform QC testing (some hands-on on one pieces of EQ): BacT, NC-200, flow cytometry, Endotoxin, etc.
 - Perform a device qualification as case study (Hands on: IOPQ: record vendor info, collect C of A, record testing results, etc.)
 - Release product for the patient (C of A / check list, labeling, identification, etc.)
- 11:50 pm to 12:05 pm Conclusion/Summary/Q&A – Julie Allickson/Rich Payne (*10 Min*) - (Room 250A)
- 12:15 pm to 12:40 pm Lunch with workshops (Room 250 A&B)
- 12:40 pm to 1:00 pm Shuttle to Biotech Place for RME Course Opening**

Workshop #3: BIOPRINTING

- Pre-Workshops held Monday, July 11, 2016 (9 am to 12:15 pm)
- Post-Workshops held Friday, July 15, 2016 (1:30 pm to 4:45 pm)



PRE- BIOPRINT WORKSHOP -- Monday, July 11th – Morning Schedule

9:00 am to 9:20 am	Introduction – John Jackson (Room 250 B) Incorporating
9:20 am to 9:40 am	medical imaging into bioprinting – Carlos (Room 250 B)
	<ol style="list-style-type: none">1. CT and MRI images2. 3D CAD<ul style="list-style-type: none">- Reverse engineering3. 3D CAM<ul style="list-style-type: none">- Motion command4. Bioprinting<ul style="list-style-type: none">- Layer-by-layer manufacturing
9:40 am to 11:30 am	Bioprinting demonstrations
9:40 am to 10:00 am	1. Piezoelectric bioprinting - Ashkan (Room 341)
10:00 am to 10:45 am	2. Biobots - Cabrera and Solorzano (Room 342)
10:45 am to 11:30 am	3. Extrusion-based bioprinting - Young-Joon, Zhan, Prafulla (Room 296) <ol style="list-style-type: none">i. Bioprinting materials<ol style="list-style-type: none">a. Synthetic biopolymers for structural stability of constructsb. Bio-inks for maintenance of cell viability in constructs
11:30 am to 12:00 pm	Closing remarks – panel discussion with Q&A (Room 250 B)
12:00 to 12:40 pm	Lunch with both workshops (Room 250 B)
12:40 pm to 1:00 pm	Shuttle to Biotech Place for RME Course Opening

Workshop #3: BIOPRINTING

POST BIOPRINT WORKSHOP Friday, July 15th – Afternoon Schedule

(Shuttle from Biotech Place to WFIRM at 1:00-1:15pm, Workshops room 1:30 pm to 4:45 pm)

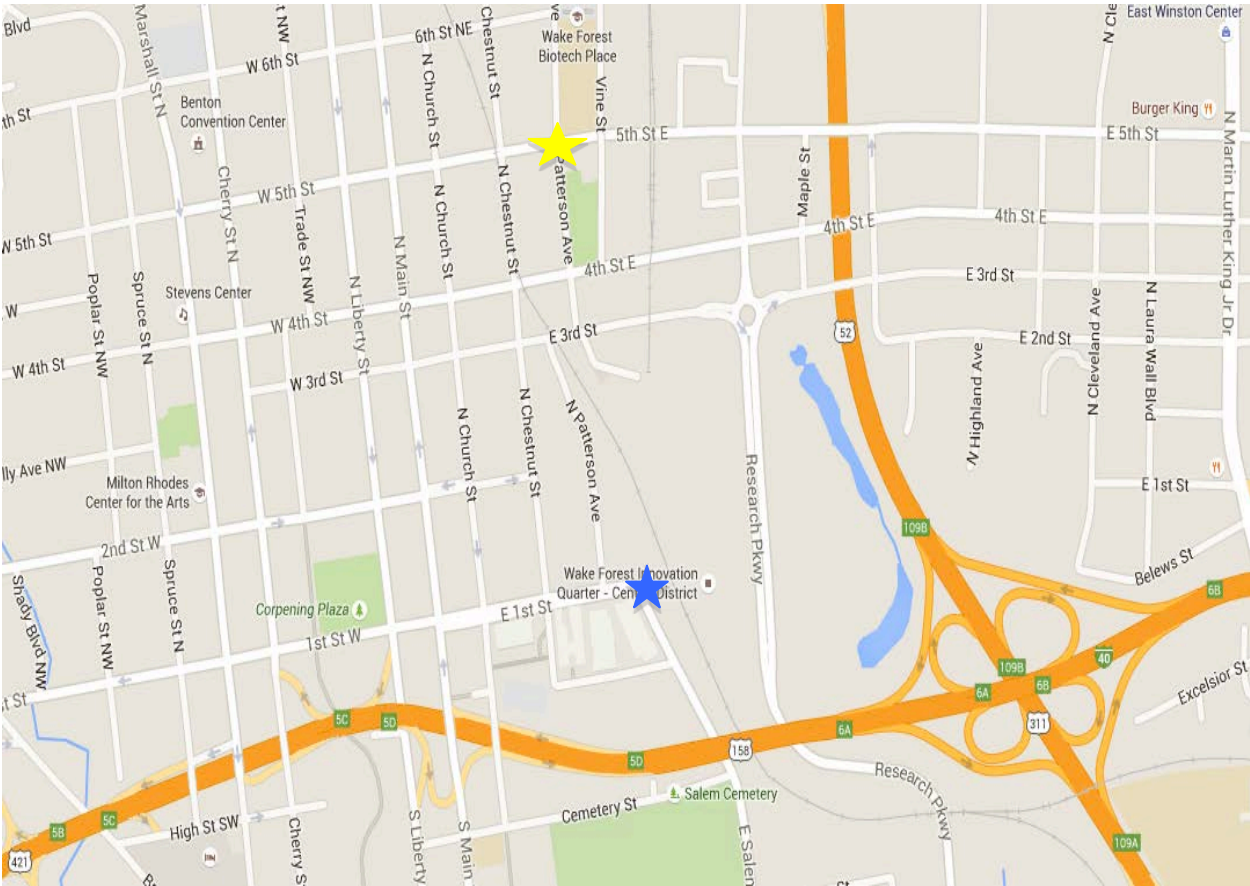


1:30 pm to 1:50 pm	Introduction – John Jackson (Room 250 B) Incorporating medical imaging into bioprinting – Carlos (Room 250 B)
1:50 pm to 2:10 pm	
	<ol style="list-style-type: none">1. CT and MRI images2. 3D CAD<ul style="list-style-type: none">- Reverse engineering3. 3D CAM<ul style="list-style-type: none">- Motion command4. Bioprinting<ul style="list-style-type: none">- Layer-by-layer manufacturing
2:10 pm to 4:00 pm	Bioprinting demonstrations
2:10 pm to 2:30 pm	1. Piezoelectric bioprinting - Ashkan (Room 341)
2:30 pm to 3:15 pm	2. Biobots - Cabrera and Solorzano (Room 342)
3:15 pm to 4:00 pm	3. Extrusion-based bioprinting - Young-Joon, Zhan, Prafulla (Room 296) <ol style="list-style-type: none">ii. Bioprinting materials<ol style="list-style-type: none">a. Synthetic biopolymers for structural stability of constructsb. Bio-inks for maintenance of cell viability in constructs
4:00 pm to 4:30pm	Closing remarks – panel discussion with Q&A (Room 250B)

With Special Thanks to our Workshop Sponsor and Exhibitor:

3iobots

Shuttle Drop Off/Pick-Up Locations



Yellow Star- pick up/drop off at Biotech place; **Blue Star**- pick up drop off at WFIRM