

# National Regenerative Medicine Manufacturing Innovation Center (NRMMIC)

## Industry Focus Group - Working Agenda May 20, 2015 in Charlotte, NC DoubleTree by Hilton Charlotte Airport

**Meeting Objectives:** (1) Vision and Mission of the Innovation Center; (2) Challenges and Opportunities in Regenerative Medicine; (3) Identify Projects of Interest for the National Regenerative Medicine Manufacturing Innovation Center; (4) IP Strategy;

8:30 AM	Continental Breakfast
9:30 AM	Welcome, and Vision and Mission of the NRMMIC
10:00 AM	Manufacturing Challenges for TERM Technologies: Survey Results from Industry on our Manufacturing Road Map to TERM Technologies [Josh Hunsberger]
10:15 AM	Break Out Sessions

Break Out Session 1: RM Therapeutic Breakout Session (groups of 4-6 people)	
Format	Group Options / Leads
<ul style="list-style-type: none"> <li>Group Discussion – 25 minutes</li> <li>Report out to total group – 15 min (2-3 minutes per group)</li> <li>Summary &amp; Group total group input – 15 min</li> </ul>	<ul style="list-style-type: none"> <li>Syed Hossainy (Abbott)</li> <li>Greg Russotti (Celgene)</li> <li>Gail Naughton (Histogen)</li> <li>Carl Burke (Jansen)</li> <li>Dave McGuigan (Stemedica)</li> </ul>

**Break– 10 min**

Break Out Session 2: RM Tools, Technologies, & Devices Breakout Session (groups of 4-6 people)	
Format	Group Options / Leads
<ul style="list-style-type: none"> <li>Group Discussion – 25 minutes</li> <li>Report out to total group – 15 min (2-3 minutes per group)</li> <li>Summary &amp; Group total group input – 15 min</li> </ul>	<ul style="list-style-type: none"> <li>Martin Brown (GE Healthcare)</li> <li>Ken Burhop (Integra)</li> <li>Steven Lynum (Panasonic)</li> <li>Colleen Wivell (Materialise)</li> <li>Martha Rook (EMD Millipore)</li> </ul>

12:45 PM LUNCH BREAK & NETWORKING

2:00 PM Intellectual Property and Consortium Models: Overview

2:15 PM Break Out Session

<b>Break Out Session 3: Consortium Models: Focus on developing pre-competitive space (groups of 4-6 people)</b>	
<b>Format</b>	<b>Group Options / Leads</b>
<ul style="list-style-type: none"><li>• <b>Group Discussion – 25 minutes</b></li><li>• <b>Report out to total group – 15 min (2-3 minutes per group)</b></li><li>• <b>Summary &amp; Group total group input – 15 min</b></li></ul>	<ul style="list-style-type: none"><li>• Kathy Loper (AABB)</li><li>• Kirsten Crapnell (BD Technologies)</li><li>• Rolf Müller (Biomatrica)</li><li>• Mohan Vemuri (Thermo Fisher)</li><li>• Uplaksh Kumar (RoosterBio)</li></ul>

3:30 PM Conclusions & Future Directions

4:00 PM Networking

4:30 PM Adjourn

## Manufacturing Road Map for Tissue Engineering and Regenerative Medicine Technologies

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JAMES YOO,<sup>a</sup> ANTHONY ATALA<sup>a</sup>

- Create an industry-driven consortium to **develop infrastructure and resources** to advance manufacturing know-how and capacity in TERM
- Create a set of **standards** for biologics, tissue-engineered, and combination products to navigate regulatory challenges and speed up translation/commercialization
- Incentivize **precompetitive space** to develop, innovate, and socialize exponential improvements in advanced manufacturing science (design of production processes, production equipment, and control infrastructures) that can be applied seamlessly to TERM product development
- Create a **TERM Manufacturing Innovation Education and Workforce Development Consortium**, leveraging and creating training and education programs that incorporate topics integral to all aspects of TERM manufacturing to target all educational levels