Workshop on Characterization of Fiber-Based Scaffolds

Sponsored by ARMI | BioFabUSA & ASTM
with participation from Standards Coordinating Body
Background

• At a 2013 ASTM workshop on scaffold measurements determined that the major measurement needs were 1) structural, 2) mechanical and 3) biological
• Fiber-based scaffolds are being widely advanced in tissue engineering for a wide variety of applications.
• Focus:
  • scaffold characterization
  • batch to batch variability
  • measurement validation
  • process controls
  • release criteria
  • comparability
  
  “make practical the large scale manufacturing of engineered tissues”
  
  “well-characterized & reproducible”
  
  “The focus is not on making a few prototypes for a first in human study, the focus is on making one million units”
Potential Workshop Outcomes

1. Workshop report to summarize findings & discussion

2. Form working group to write an “ASTM Standard Guide for Characterizing Fiber-Based Scaffolds”

3. Form working group to address “Porosity”

4. Form working group to address “Diffusivity”
<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
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<tbody>
<tr>
<td>9:00 - 9:15</td>
<td>Welcome, Opening Remarks, Becky Robinson-Zeigler (ARMI), Carl Simon (NIST)</td>
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<tr>
<td>9:15 - 9:40</td>
<td>Talk #1: Michael Yaszemski, Mayo Clinic</td>
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<td>9:40 - 10:05</td>
<td>Talk #2: Michael Francis, Embody LLC</td>
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<td>10:05 - 10:30</td>
<td>Talk #3: Jayesh Doshi, eSpin</td>
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<td>10:30 - 10:45</td>
<td>Break</td>
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<td>10:45 - 11:10</td>
<td>Talk #4: Luca Cera, Harvard,</td>
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<td>11:10 - 11:35</td>
<td>Talk #5: Alex Meltzer, DiPole Materials</td>
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<td>11:35 - 12:00</td>
<td>Talk #6: Seth McCullen, Poly-Med, Inc.</td>
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<td>12:00 - 1:00</td>
<td>Lunch</td>
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<td>1:00 - 1:10</td>
<td>Intro to the Breakout Sessions, “Measurements most in need of improvement” (Carl Simon)</td>
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<tr>
<td>1:10 - 1:25</td>
<td>Porosity Introduction&lt;br&gt;Discussion Leaders: Thomas Bollenbach (ARMI), Markus Reiterer (Medtronic)</td>
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<td>1:25 - 1:40</td>
<td>Diffusivity Introduction&lt;br&gt;Discussion Leaders: Esmaiel Jabbari (S. Carolina Univ.), Ramon Montero (Akron Biotech), Hai Yao (Clemson)</td>
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<td>1:40 - 2:55</td>
<td>Concurrent Breakout Sessions&lt;br&gt;Measurement #1: Porosity (break into 2 or 3 small groups)&lt;br&gt;Measurement #2: Diffusivity (break into 2 or 3 small groups)</td>
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<td>2:55 - 3:35</td>
<td>Networking computer-poster session</td>
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<td>3:35 - 4:05</td>
<td>Report-out for Porosity</td>
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<tr>
<td>4:05 - 4:35</td>
<td>Report-out for Diffusivity</td>
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<td>4:35 - 5:00</td>
<td>Discussion &amp; Wrap-Up: workshop report, ASTM standards, formation of working groups</td>
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<td>5:00</td>
<td>Adjourn</td>
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Measurement Variability vs. Product Variability

- Measurement Variability (today’s focus): Variability in a measurement process
- Product Variability: Variability in the properties of the fiber-based scaffold
- Both are important.
- It is a chicken or the egg phenomena

You can’t assess a measurement system without specimens with consistent properties
You can’t assess product variability without good measurements
Attendee Demographics

- **Industry**: 59%
  - Poly-Med
  - IME
  - Tepha
  - Embody
  - 3D Biotek
  - Nanofiber Solutions
  - LifeSprout Inc
  - Medtronic
  - DEKA
  - ATEX Technologies
  - The Electrospinning Co.
  - Biorez
  - Akron Biotech
  - DiPole Materials
  - eSpin Technologies
  - Humacyte
  - Electrospinning BioInnovations Grp

- **Non-Profit**: 16%
  - ARMIS
  - CBASTM

- **Academic**: 20%
  - Harvard
  - Ga Tech
  - Drexel
  - Univ S. Carolina
  - Tufts
  - Mayo Clinic
  - Univ Memphis
  - Clemson
  - UIUC

- **Government**: 7%
  - Nat’l Res. Council
  - NIST

- **Gov’t**: 5%
  - 2

Total Attendees: 26
Thanks to Those that Helped Organize

Organizing Committee
Carl Simon
Mike Yaszemski
Michael Francis
Jayesh Doshi
Sherif Soliman

ARMI | BioFabUSA
Becky Robinson-Zeigler
Lexi Garcia
Richard McFarland

ASTM
Kate Chalfin
Kelly Dennison

Speakers
Luca Cera
Alex Meltzer
Seth McMullen

Breakout Session Organizers
Tom Bollenbach
Markus Reiterer
Esmaiel Jabbari
Ramon Montero
Claudia Zylberberg
Hai Yao

Standards Coordinating Body
Dawn Henke
Allison Getz