FDA/NIST Sponsored Workshop *In Vitro* Analyses of Cell/Scaffold Products

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Workshop Objectives:

- To learn what questions should be asked when evaluating a cell/scaffold product in preparation for the first human studies.

- To learn what *in vitro* test methods are available and what analytical procedures need to be further researched, developed and/or standardized to determine the safety, purity, potency and consistency of cell/scaffold products.

In Vitro Analyses of Cell/Scaffold Products Workshop - Overview

SESSION 1: *In Vitro*/Bench Top Characterization of Cell/Scaffold Products

- **Overview of Cellular Biomarkers –**
  Rocky Tuan, Ph.D. National Institutes of Health

- **Overview of Biomaterials Characterization**
  Buddy Ratner, Ph.D. U. of Washington

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- ***In vitro* Characterization of Hard Tissue Constructs with Structural Role -** David Kaplan, Ph.D. Tufts University
- ***In vitro* Characterization of Skin Constructs with a Structural Role -** Nancy Parenteau, Ph.D. Parenteau BioConsultants, LLC
- ***In vitro* Characterization of Cardiovascular Constructs with a Structural Role -** Keith Gooch, Ph.D. Ohio State University
- ***In vitro* Characterization of a Bladder Construct -** Tim Bertram, D.V.M., Ph.D. Tengion, Inc.

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- ***In vitro* Characterization of a Pancreatic Islet Construct -** Melissa Carpenter, Ph.D. NovoCell, Inc.
- ***In vitro* Characterization of an *Ex Vivo* Liver Construct -** Scott Nyberg, M.D., Ph.D. Mayo Clinic
- ***In vitro* Characterization of a Fetal Lung Construct -** Peter Lelkes, Ph.D. Drexel University
- **Potency Assays -** Kimberly Benton, Ph.D. FDA/CBER
- **Roundtable Discussion**

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SESSION 2: Systematic and High Throughput Analyses of Cell/Scaffold Products

- **MATES IWG and MATES Strategic Plan -** Fred Heineken, Ph.D. - *National Science Foundation (NSF)*
- **Trends in Tools and Strategies for Quantifying Biological Response** - Anne Plant, Ph.D. *National Institute of Standards and Technology (NIST)*

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- **Commercial Assay Development and Quantification** - Ken Giuliano, Ph.D. Cellumen, Inc.
- **Automated Algorithms for High Content Microscopy** - Lani Wu, Ph.D. University of Texas, Southwestern Medical Center
- **Proteomics of Cell Scaffold Constructs** - Dan Martin, Ph.D. Institute for Systems Biology
- **Analysis and Manipulation of Cell Adhesion Receptors and Extracellular Matrix Ligands** - Andres Garcia, Ph.D. - Georgia Institute of Technology

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- **Novel Methods to Quantify Tissue Structure and Multi-Axial Mechanical Testing -** Michael Sacks, Ph.D. University of Pittsburgh
- **Considerations for Quality Control of *In Vitro* Cell Cultures -** John Elliott, Ph.D. - National Institute of Standards and Technology (NIST)
- **Roundtable Discussion**
- **Rapporteur Presentation -** Robert Nerem, Ph.D. - Georgia Institute of Technology
- **Concluding Discussion**

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