



University of Maryland Center for Excellence in Regulatory
Science and Innovation
Science that speeds health innovation



UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE
CENTER FOR STEM CELL BIOLOGY
AND REGENERATIVE MEDICINE

Workshop on Improved Characterization of Mesenchymal Stem Cells for Clinical Trials

Mark your calendars for the Workshop on Improved Characterization of Mesenchymal Stem Cells (MSC) for Clinical Trials, sponsored by the University of Maryland Center for Excellence in Regulatory Science and Innovation (M-CERSI), the University of Maryland School of Medicine's Center for Stem Cell Biology and Regenerative Medicine and Department of Orthopaedics, and the Food and Drug Administration.

The Workshop on Improved Characterization of Mesenchymal Stem Cells for Clinical Trials will be held on **Wednesday, May 8, 2013**, in the Southern Management Corporation Campus Center at the University of Maryland, Baltimore, located at 621 West Lombard Street in Baltimore, MD.

The goal of this one-day workshop is to assess MSC characterization and discuss methods that can be used to predict the quality, potency, and safety of MSCs, with implications for other types of stem cells and cell-based products.

For more information, please visit www.pharmacy.umaryland.edu/msc.



Registering by mail? Please detach this form and submit it with your check. All participants can also register online at www.pharmacy.umaryland.edu/msc, which accepts credit cards.



Workshop on Improved Characterization of Mesenchymal Stem Cells for Clinical Trials Mail-In Registration

Please make check payable to **UMBF/CERSI** and mail to:

University of Maryland School of Pharmacy
Attn: Sharese Essien
20 Penn Street
HSF II, Room 518
Baltimore, MD 21201

Please provide the following information:

Name

Address

Phone

Email

Title and Company/School/Agency

Please indicate highest degree obtained:

- High School Master's Degree
 Bachelor's Degree Doctorate

Please indicate which category best describes you:

- Faculty, Staff, Student from the University of Maryland, Baltimore or College Park Campus (FREE)
 Federal Government Employee (FREE)
 Any Full-Time Student (FREE)
 M-CERSI Industrial Consortia Members (FREE)
 Other Participant (\$50.00)

WORKSHOP AGENDA

May 8, 2013

8:00 a.m.

Welcome from the UM Center for Stem Cell Biology & Regenerative Medicine

Curt Civin, MD
 Director, Center for Stem Cell Biology & Regenerative Medicine
 Associate Dean for Research
 Professor of Pediatrics and Physiology
 University of Maryland School of Medicine

Welcome from the Food and Drug Administration

Frank Weichold, PhD
 Director of Regulatory Science and Innovation
 Food and Drug Administration

8:10 a.m.

Meeting Introduction: "What Should You Measure to Characterize Your MSCs for Clinical Use and What Can We Learn from Animal Models"

Curt Civin, MD
 Director, Center for Stem Cell Biology and Regenerative Medicine
 Associate Dean for Research
 Professor of Pediatrics
 University of Maryland School of Medicine

Steven R. Bauer, PhD
 Chief, Cell and Tissue Therapy Branch
 Division of Cellular and Gene Therapies
 Office of Cellular, Tissue, and Gene Therapies
 FDA/Center for Biologics Evaluation and Research

Workshop Moderator: Joseph Stains, PhD
 Assistant Professor of Orthopaedics and Physiology
 Department of Orthopaedics
 University of Maryland School of Medicine

8:15 a.m.

"History and Clinical Development of MSCs"

Arnold I. Caplan, PhD
 Director, Skeletal Research Center
 Professor of Biology
 Professor of General Medical Sciences (Oncology)
 Case Western Reserve University

8:45 a.m.

"Imaging and Applications of MSCs in Pre-Clinical Animal Models"

Dara L. Kraitchman, VMD, PhD, FACC
 Associate Professor, Department of Radiology
 Section Head, Cardiovascular Intervention
 Johns Hopkins University

9:15 a.m.

"International Society for Cell Therapy's Perspective on Characterization of MSCs for Clinical Trials"

Donald G. Phinney, PhD
 Professor, Department of Molecular Therapeutics
 The Scripps Research Institute

9:45 a.m.

"Characterization of MSCs for Clinical Application"

Jacques Galipeau, MD, FRCP(C)
 Co-Director, Winship Cancer Institute Tumor Immunology-Immunotherapy
 Director, Emory Personalized Immunotherapy Center [EPIC]
 Professor of Hematology and Medical Oncology
 Professor of Pediatrics & Medicine
 Emory University

10:15 a.m.

"Clinical Application of MSCs"

Stanton Gerson, MD
 Asa and Patricia Shiverick -- Jane Shiverick (Tripp) Professor of Hematological Oncology
 Director, Case Comprehensive Cancer Center
 Director, National Center for Regenerative Medicine
 Case Western Reserve University

10:45 a.m.

Break

11:00 a.m.

"Industry Perspective/Experience with MSC Characterization"

Robert Deans, PhD
 Executive Vice President, Regenerative Medicine
 Athersys, Inc.

11:30 a.m.

"Systems Biology/Bioinformatics and Characterization of Stem Cell-Based Cell Therapy Products"

Amitabh Varsheny, PhD
 Director, University of Maryland Institute for Advanced Computer Studies
 Professor of Computer Science
 University of Maryland, College Park

Carol G. Simon, Jr., PhD
 Biologist, Biosystems & Biomaterials Division
 Biomaterials Group
 Material Measurement Laboratory
 National Institute of Standards and Technology

12:00 p.m.

"FDA Perspectives on MSC Characterization and the MSC Consortium"

Steven R. Bauer, PhD
 Chief, Cell and Tissue Therapy Branch
 Division of Cellular and Gene Therapies
 Office of Cellular, Tissue, and Gene Therapies
 FDA/Center for Biologics Evaluation and Research

12:30 p.m.

Panel Discussion

Chair: Mark Pittenger, PhD
 Chief Science Officer
 Pearl Lifesciences Partners

1:00 p.m.

Adjourn