International Society for Cellular Therapy
ISCT

8th Annual Somatic Cell Therapy Symposium 2008 Program

Monday, September 22, 2008

Optional Introductory Program for delegates new to the field. $50 Fee Required.

7:00 - 5:00pm	**Registration** Crystal Ballroom Foyer
8:00 - 9:00am	**Breakfast** Crystal Ballroom Foyer
9:00 - 9:05am	**Welcome** Crystal Ballroom Elizabeth J Read, MD Director, Cell and Tissue Therapies, Blood Systems Research Institute, Adjunct Professor of Laboratory Medicine, University of California, San Francisco
9:05 - 10:30am	**Introduction to the Regulation of Cellular Therapies** Crystal Ballroom **Chair: Lynn O'Donnell, PhD** Director, Cell Therapy Laboratory, James Cancer Hospital & Research Institute, Ohio State University Mercy Quagraine, PhD OCTGT, CBER, FDA
10:30 - 11:30am	**Introduction to IND Preparation** Crystal Ballroom **IND Overview:** **Darin Weber, PhD** Senior Consultant, Biologics Consulting Group, Inc CMC Section: Janice Davis-Sproul, MAS Manager, Cell Therapy & Development Laboratory, Johns Hopkins Medicine

Monday, September 22, 2008 (continued)

Regular Program

11:50 - 12:50pm	**Corporate Sponsored Lunch Session** **Cellgenix, AFC, Terumo** Crystal Ballroom Three talks aimed at describing current developments in sterile closed system cell processing, validation procedures, and related clinical experience. Lunch available in the Crystal Ballroom Foyer
1:00 - 1:10pm	**Welcome** Crystal Ballroom Elizabeth J Read, MD Director, Cell and Tissue Therapies, Blood Systems Research Institute, Adjunct Professor of Laboratory Medicine, University of California, San Francisco

Monday, September 22, 2008 (continued)

1:10 – 2:40pm	**FDA Update & Overviews** Crystal Ballroom CBER/OCTGT Update Celia Witten, MD, PhD Director, OCTGT, CBER, FDA **Challenges of Product Development** **Darin Weber, PhD** Senior Consultant, Biologics Consulting Group **Approaches to Risk Assessment for Cellular Therapies** **Brian Flynn** Quality Manager, Genzyme Biosurgery
2:40 – 3:30pm	**Qualification of Ancillary Reagents I** Crystal Ballroom **Chair: Bruce Levine, PhD** Director, Clinical Cell &Vaccine Production Facility, University of Pennsylvania **FDA Perspective** **Steven Oh, PhD** OCTGT, CBER, FDA Standards Setting for Ancillary Materials: USP Perspective **Fouad Atouf PhD** Scientist, Biologics and Biotechnology, U.S. Pharmacopeia Standards Setting for Ancillary Materials: Industry Perspective Gary du Moulin, PhD, MPH, RAC Senior Director, Quality Compliance Genzyme Biosurgery
3:30 – 4:00pm	**Break & Exhibits** Crystal Ballroom Foyer
4:00 – 5:00pm	**Qualification of Ancillary Reagents II** Crystal Ballroom **Panel Presentations & Discussion:** Bruce Levine, PhD // Fouad Atouf, PhD // Gary du Moulin, PhD, MPH, RAC // Julia Goldstein, MD Senior Regulatory Affairs Officer, Office of Regulatory Affairs, NIAID, NIH
5:00 – 6:10pm	**Challenges of International Studies from the Regulatory and Business Perspectives** Crystal Ballroom **Chair: Lee Buckler, BEd, LLB** Business Development, Progenitor Cell Therapy, LLC **Panel Presentations & Discussion:** **Christopher Bravery, PhD** Director of Regulatory Affairs (UK), ERA Consulting Elmar Burchardt, MD, PhD Vice President Medical Affairs, Aastrom Biosciences, Inc **Kelly Ganjei** Toucan Capital Corp.
6:30 – 7:30pm	**Welcome Reception** Crystal Ballroom Foyer

Tuesday, September 23, 2008

7:00 – 4:00pm	**Registration** Crystal Ballroom Foyer
7:40 – 8:40am	**Corporate Sponsored Breakfast Sessions** **USP** Old Georgetown Developing Standards for Cell and Gene Therapy Products Biologics and Biotechnology at the United States Pharmacopeia (USP). Breakfast available in the Old Georgetown Foyer **Invitrogen** Cabinet/Judiciary Preparing for commercialization: Case studies in productivity enhancement and risk mitigation for cell therapy manufacturing. Breakfast available in the Cabinet/Judiciary Foyer
8:55 – 9:00am	**Introduction** Crystal Ballroom
9:00 – 10:30am	**Novel Therapies & Enabling Technologies** Crystal Ballroom **Chair: Shelly Heimfeld, PhD** Director, Cellular Therapy Laboratory & cGMP Cell Processing Facility, Fred Hutchinson Cancer Research Center **Iron Labeling of CD133+ Cells** Joseph A. Frank, MD Chief, Laboratory of Diagnostic Radiology Research, Clinical Center, NIH **Adipose-Derived Stem Cells for Peripheral Vascular Disease** Keith L. March, MD, PhD Director, Indiana Center for Vascular Biology & Medicine, Indiana University **Cell Sorting for Cellular Therapeutics** **Andrew Balber, PhD** Chief Scientific Officer, Aldagen
10:30 - 11:00am	**Break & Exhibits** Crystal Ballroom Foyer
11:00 – 12:30pm	**Novel Therapies** Crystal Ballroom Chair: David McKenna Jr., MD Medical Director, Clinical Cell Therapy Lab, University of Minnesota Medical Center **Non-Homologous Use of Cord Blood** Mary J. Laughlin, MD Associate Professor of Medicine and Pathology, Case Western Reserve University, Cleveland Cord Blood Center **Development of Muscle Cell Therapy for Incontinence** **Ron Jankowski, PhD** Director, Research & Product Development, Cook MyoSite, Inc. **Retinal Progenitor Cells** **Jonathan Dinsmore, PhD** Senior Vice President and General Manager, Advanced Cell Technology & Mytogen, Inc.

Tuesday, September 23, 2008 (continued)

12:40 – 2:00pm	**Lunch & Presentations** Update from the ISCT Legal & Regulatory Committee Kurt Gunter, MD Hospira, Inc. **CT Laboratories – How to get the Reimbursement You Deserve** John McMannis, PhD Director, Cell Processing Laboratory, MD Anderson Cancer Center Lunch available in the Crystal Ballroom Foyer
2:00 – 3:30pm	**Challenges for Manufacturing, Shipping, and On-site Preparation of CT Products** Crystal Ballroom **Chair: Carolyn Keever-Taylor, PhD** Director, BMT Processing Laboratories, Medical College of Wisconsin **Panel Presentations & Discussion:** David McKenna Jr., MD University of Minnesota Medical Center **Robert Preti, PhD** President & CSO, Progenitor Cell Therapy, LLC **Jerrod Denham** Senior Manager, Manufacturing Sciences, Geron Corporation **Brian Flynn** Quality Manager, Genzyme Biosurgery
3:30 – 4:00pm	**Break & Exhibits** Crystal Ballroom Foyer
4:00 – 5:30pm	**US Government Funding of Cellular Therapies** Crystal Ballroom **Chair: Liana Harvath, PhD** NHLBI, NIH **Panel Presentations & Discussion:** Traci Mondoro, PhD NHLBI, NIH Lili Portilla, MPA National Center for Research Resources, NIH Mrunal Chapekar, PhD National Institute of Standards and Technology **Robert Baitty** Health Resources and Services Administration **David Badman, PhD** RAID Program, NIH

Wednesday, September 24, 2008

7:00 – 12:00pm	**Registration** Crystal Ballroom Foyer
7:15 – 8:15 am	**Breakfast** Crystal Ballroom Foyer
8:20 – 8:30am	**Introduction** Crystal Ballroom

Wednesday, September 24, 2008 (continued)

8:30 – 10:00am	**Manufacturing Challenges: Operational Issues & Reports to the FDA** Crystal Ballroom Panel Chairs: Lynn O'Donnell, PhD // Janice Davis-Sproul, MAS **Panel Presentations & Discussion:** **Thomas Finn, PhD** OCTGT, CBER, FDA **Katie Faria** Director, Process Development, Organogenesis Inc. Gary du Moulin, PhD, MPH, RAC Senior Director, Quality Compliance, Genzyme Biosurgery
10:00 – 10:30am	**Break** Crystal Ballroom Foyer
10:30 – 12:00pm	**Product Nomenclature** Crystal Ballroom Chair: John McMannis, PhD Director, Cell Processing Laboratory, MD Anderson Cancer Center **Kimberly Benton, PhD** Deputy Director, Division of Cellular & Gene Therapies, OCTGT, CBER, FDA **Lilia Bi** OCTGT, CBER, FDA **Darin Weber, PhD** Senior Consultant, Biologics Consulting Group, Inc **Fran Rabe,** Manager of Quality Assurance, University of Minnesota

CO-CHAIRS:

Elizabeth J Read MD, University of California, San Francisco

Janice Davis-Sproul MAS, MT(ASCP) Johns Hopkins Medicine

ORGANIZING COMMITTEE MEMBERS:

Kimberly Benton, PhD OCTGT, CBER, FDA

Lee Buckler, BEd, LLB, Progenitor Cell Therapy, LLC

Liana Harvath, PhD, NHLBI, NIH

Shelly Heimfeld, PhD, Fred Hutchinson Cancer Research Center

Carolyn Keever-Taylor, PhD, Medical College of Wisconsin

Mary Laughlin, MD, Case Western Reserve University

Bruce Levine, PhD, University of Pennsylvania

John McMannis, PhD, MD Anderson Cancer Center

David McKenna, MD, University of Minnesota Medical Center

Lynn O'Donnell, PhD, Ohio State University