



8th Annual Somatic Cell Therapy Symposium 2008

Preliminary Program

Note: This Preliminary Program lists confirmed speakers only and will be updated as necessary.

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

Monday, September 22, 2008		
7:30 – 8:30 am	Registration & Breakfast	
8:40 – 8:50 am	Welcome	Elizabeth J Read, MD Director, Cell and Tissue Therapies Blood Systems Research Institute Clinical Professor of Laboratory Medicine University of California, San Francisco
8:50 – 9:50 am	Introduction to the Regulation of Cellular Therapies	Chair: Lynn O'Donnell, PhD Director, Cell Therapy Laboratory James Cancer Hospital & Research University of Ohio Ellen Lazarus, MD, FCAP Captain, US Public Health Service Medical Officer, Division of Human Tissues OCTGT, CBER, FDA
9:50 – 10:20 am	Break	
10:20 – 11:20 am	Introduction to IND Preparation	IND Overview: Darin Weber, PhD Senior Consultant, Biologics Consulting Group, Inc CMC Section: Janice Davis-Sproul, MAS Manger, Cell Therapy & Development Laboratory Johns Hopkins Medicine

Monday, September 22, 2008		
9:00 - 1:00 pm	Registration	
11:45 - 12:45 pm	Corporate Sponsored Lunch Sessions	
1:00 - 1:10 pm	Welcome	Elizabeth J Read, MD Blood Systems Research Institute University of California, San Francisco
1:10 - 2:40 pm	FDA Update & Overviews	<p>CBER/OCTGT Update Celia Witten, MD, PhD Director, OCTGT, CBER, FDA</p> <p>Challenges of Product Development Darin Weber, PhD Senior Consultant, Biologics Consulting Group</p> <p>Approaches to Risk Assessment for Cellular Therapies Brian Flynn Quality Manager, Genzyme Biosurgery</p>
2:40 - 3:30 pm	Qualification of Ancillary Reagents I	<p>Chair: Bruce Levine, PhD Director, Clinical Cell & Vaccine Production Facility, University of Pennsylvania</p> <p>FDA Perspective Steven Oh, PhD OCTGT, CBER, FDA</p> <p>Standards Setting for Ancillary Materials: USP Perspective Fouad Atouf Ph.D. Scientist, Biologics and Biotechnology U.S. Pharmacopeia</p> <p>Standards Setting for Ancillary Materials: Industry Perspective Gary duMoulin, PhD, MPH, RAC Senior Director, Quality Compliance Genzyme Biosurgery</p>
3:30 - 4:00 pm	Break	

4:00 – 5:00 pm	Qualification of Ancillary Reagents II	Panel Discussion: Bruce Levine, PhD Fouad Atouf Ph.D. Gary duMoulin, PhD, MPH, RAC Julia Goldstein, MD Sr. Regulatory Affairs Officer, Office of Regulatory Affairs, NIAID, NIH
5:00 – 6:10 pm	Challenges of International Studies from the Regulatory and Business Perspectives	Chair: Lee Bucker, BEd, LLB Business Development, Progenitor Cell Therapy, LLC Panelists: 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 – 7:30 pm	Reception	

Tuesday, September 23, 2008		
7:40 – 8:40 am	Corporate Sponsored Breakfast Sessions	
8:55 – 9:00 am	Introduction	
9:00 – 10:30 am	Novel Therapies & Enabling Technologies	Chair: Shelly Heimfeld, PhD Director, Cellular Therapy Laboratory & cGMP Cell Processing Facility Fred Hutchinson Cancer Research Iron Labeling of CD133⁺ Cells Joseph A. Frank, M.D. Chief, Laboratory of Diagnostic Radiology Research, National Institutes of Health Adipose-Derived Stem Cells for PVD Keith L. March, M.D. PhD Director, Indiana Center for Vascular Biology & Medicine Cell Sorting for Cellular Therapeutics Andrew Balber, PhD Chief Scientific Officer, Aldagen

10:30 - 11:00 am	Break	
10:45 - 12:15 pm	Novel Therapies	<p>Chair: David McKenna Jr., MD Medical Director, Clinical Cell Therapy Lab University of Minnesota Medical Center</p> <p>Non-Homologous Use of Cord Blood Mary J. Laughlin, MD Associate Professor of Medicine and Pathology, Case Western Reserve University, Cleveland Cord Blood Center</p> <p>Encapsulated Insulin-Producing Porcine Islet Cells Speaker: TBA</p> <p>Retinal Progenitor Cells Jonathan Dinsmore, Ph.D S.V.P. and General Manager Advanced Cell Technology & Mytogen, Inc.</p>
12:30 - 2:00 pm	Lunch	
	Update from the ISCT Legal & Regulatory Committee CT Laboratories - How to get the Reimbursement You Deserve	
2:00 - 3:30 pm	Challenges for Manufacturing, Shipping, and On-site Preparation of CT Products	<p>Chair: Carolyn Keever-Taylor, PhD Director, BMT Processing Laboratories Medical College of Wisconsin</p> <p>Panelists:</p> <p>David McKenna Jr., MD University of Minnesota Medical Center</p> <p>Robert Preti, PhD President, CSO Progenitor Cell Therapy, LLC</p> <p>Jerrold Denham Senior Manager, Manufacturing Sciences, Geron Corporation</p> <p>Brian Flynn Genzyme Biosurgery</p>
3:30 - 4:00 pm	Break	
4:00 - 5:30 pm		Chair: Liana Harvath, PhD

	<p>US Government Funding of Cellular Therapies</p>	<p>Panelists: Traci Mondoro, PhD NHLBI, NIH Lili Portilla, MPA NCCR, NIH Mrunal Chapekar, PhD NIST Robert Baitty HRSA David Badman, PhD NIH, RAID Program</p>
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Wednesday, September 24, 2008		
7:15 – 8:15 am	Corporate Sponsored Breakfast Session	
8:20 – 8:30 am	Introduction	
8:30 – 10:00 am	<p>Manufacturing Challenges: Operational Issues & Reports to the FDA</p>	<p>Panel Chairs: Lynn O'Donnell, PhD Janice Davis-Sproul, MAS</p> <p>Panelists: Thomas Finn, PhD OCTGT, CBER, FDA Katie Faria Director, Process Development Organogenesis Inc. Gary duMoulin, PhD, MPH, RAC Genzyme Biosurgery</p>
10:00 – 10:30 am	Break	
10:30 – 12:00 pm	<p>Product Nomenclature</p>	<p>Chair: John McMannis, PhD Director, Cell Processing Laboratory MD Anderson Cancer Center</p> <p>Kimberly Benton, PhD Chief, Cell Therapies Branch Division of Cellular & Gene Therapies OCTGT, CBER, FDA</p> <p>Mercy Quagraine, PhD Product Reviewer, OCTGT, CBER, FDA</p> <p>Darin Weber, PhD Biologics Consulting Group, Inc</p>