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# International Society for Cellular Therapy ISCT



## Seventh Annual Somatic Cell Therapy Symposium

[www.celltherapysociety.org](http://www.celltherapysociety.org)

September 26 to 28, 2007  
Hyatt Regency Bethesda  
Bethesda, Maryland  
USA



Production Assistance for Cellular Therapies  
A National Heart Lung and Blood Institute Resource



As host of the Seventh Annual Somatic Cell Therapy Symposium, ISCT gratefully acknowledges the following companies for their unrestricted support of this meeting:

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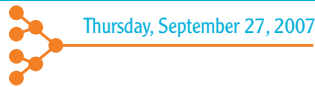
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# PROGRAM

 Wednesday, September 26, 2007

Time	Topic	Speakers
7:00 — 8:30 am	Registration & Breakfast	Breakfast served in Cabinet Foyer
7:30 — 8:30 am	Corporate Sponsored Breakfast Sessions	
	<b>Pharmanet</b> Discussion of Impact of FDA Guidance on Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells	<b>Progenitor Cell Therapy</b> Collaborating to Accelerate the Development of Cellular Therapies
	<b>Aldagen</b> "Case Study: cGMP considerations in the design, installation, and qualification of a cell therapy manufacturing facility"	
	Cabinet Suite	Judiciary Suite Old Georgetown Room
8:40 — 8:50 am	<b>Welcome</b> Crystal Ballroom	Elizabeth J Read, MD Blood Systems Research Institute
8:50 — 10:20 am	<b>Introduction to the Regulation of Cellular Therapy</b>  Crystal Ballroom	<b>Session Chair:</b> Elizabeth J Read, MD Blood Systems Research Institute  <b>CBER/OCGT Update</b> Celia Witten, MD, PhD Director, OCTGT, CBER, FDA  <b>Introduction to Cell Therapy Regulations</b> Ellen Lazarus, MD OCTGT, CBER, FDA  <b>Regulatory Perspective on the Development of Manufacturing Processes</b> Keith Wonnacott, PhD OCTGT, CBER, FDA
10:20 — 10:45 am	Coffee Break	Crystal Ballroom Foyer
10:45 — 12:15 pm	<b>Donor Issues</b>  Crystal Ballroom	<b>Panel Chair:</b> David McKenna, Jr., MD University of Minnesota Medical Center  <b>Update on Donor Issues</b> Melissa Greenwald, MD OCTGT, CBER, FDA  <b>Ruth Solomon, MD</b> OCTGT, CBER, FDA  <b>Donor Screening Challenges for Cord Blood Products</b> John Miller, MD National Marrow Donor Program  <b>Tissue Donor Testing and Screening Issues</b> Scott Brubaker, CTBS American Association of Tissue Banks  <b>Decision Analysis for Screening of HCT/P Donors</b> Brian Custer, PhD, MPH Blood Systems Research Institute
12:15 — 1:45 pm	<b>Lunch &amp; Working Group Summaries</b>  <b>Chair:</b> Shelly Heimfeld, PhD Facility Sanitization Devices Homologous Use Microbiological Testing	Crystal Ballroom

1:45 — 3:15pm	Novel Therapies I	<b>Panel Chair:</b> Bruce Levine, PhD University of Pennsylvania
	Crystal Ballroom	<b>Regulatory Challenges for The Development of Allogeneic Mesenchymal Stem Cell Product</b> Rod Monroy, PhD Osiris Therapeutics, Inc.
		<b>Application of Zinc Finger Nuclease Gene Disruption Technology to Manufacture Genetically Modified T cells for HIV Therapy</b> Bruce Levine, PhD University of Pennsylvania
		<b>PEG Encapsulated Islets for the Treatment of Diabetes</b> Xiaojie Yu, PhD Novocell Inc.
3:15 — 3:45 pm	Coffee Break	Crystal Ballroom Foyer
3:45 — 5:00 pm	Use of Devices in Manufacturing Cell Therapy Products	<b>Panel Chair:</b> Ellen Areman, MS, SBB(ASCP) Biologics Consulting Group, Inc
	Crystal Ballroom	<b>CBER Regulation of Devices for Cell Therapy</b> Richard McFarland, MD, PhD OCTGT, CBER, FDA
		<b>IDE Submissions for Devices Used to Manufacture Cell Therapy Products</b> Janice Davis-Sproul, MAS, MT(ASCP)SBB Johns Hopkins Medicine
		<b>Use of Automated Separation Devices for Cord Blood Processing</b> Safa Karandish, MT(ASCP) MD Anderson Cancer Center
		<b>Technical and Regulatory Considerations for Use of a Bioreactor in Clinical Cell Manufacturing Under an IND</b> Bruce Levine, PhD University of Pennsylvania
6:00 — 7:30 pm	Welcome Reception	Crystal Ballroom Foyer



Time	Topic	Speakers
6:50 — 8:20 am	Registration & Breakfast	Breakfast served in Cabinet Foyer
7:20 — 8:20 am	Corporate Sponsored Breakfast Sessions	
	<b>BioLife Solutions</b> Advanced Preservation Technologies: Improving Biopreservation Yield	<b>GE Healthcare</b> Focusing on Regulatory Aspects in Setting Up a GMP Facility  Cord Blood Transplantation — Maximizing Cell Viability
	Susquehanna/Severn Suite	Diplomat/Ambassador Room      Embassy/Potomat/Patuxent Room
8:20 — 8:30 am	Introduction	Crystal Ballroom Foyer
8:30 — 10:00 am	Use of Banked Cells in Manufacturing Cell Therapy Products	<b>Panel Chair:</b> Shelly Heimfeld, PhD Fred Hutchinson Cancer Research Center
	Crystal Ballroom	<b>Cell Banking: Issues and Guidance</b> Brenton McCright, PhD OCTGT, CBER, FDA

		<b>Banking of Transformed B-cell line (TM-LCL)</b> Shelly Heimfeld, PhD Fred Hutchinson Cancer Research Center
		<b>Banking Human Neural Stem Cells for Clinical Applications</b> Lisa Fox, MS, MT(ASCP) Stem Cells, Inc.
		<b>Characterization of Human Embryonic Cell Banks for the Production of Cell Based Therapies</b> Jane Lebkowski, PhD Geron Corporation
10:00 — 10:30 am	Coffee Break	Crystal Ballroom Foyer
10:30 — 12:00 pm	Novel Therapies II	<b>Panel Chair:</b> Liana Harvath, PhD Biologics Consulting Group, Inc.
	Crystal Ballroom	<b>Enhancing the Autologous and Allogeneic Anti-tumor effects of adoptive NK cell infusions</b> Richard Childs, MD NIH/NHLBI
		<b>Prevention and Treatment of Viral Infections after HLA mismatch or unrelated Allogeneic Stem Cell Transplantation with Multivirus-specific cytotoxic T Lymphocytes</b> Catherine Bollard, MD Baylor College of Medicine
		<b>Unmet Medical Needs in Ophthalmology</b> William Tente, MSc
12:00 — 1:15 pm	Lunch & Working Group Summaries	Crystal Ballroom
	<b>Chair:</b> Elizabeth J Read, MD Blood Systems Research Institute	
	<b>Update on FDA Liaison Meetings</b> Kurt Gunter, MD, Hospira, Inc.	
	<b>Update on CMS Reimbursement for Cell Therapy Products</b> James Gajewski, MD, Temple University Hospital	
1:15 — 2:45 pm	Facility & Operational Issues for Cell Therapy Facilities	<b>Panel Chair:</b> Lynn O'Donnell, PhD Ohio State University, James Cancer Hospital
	Crystal Ballroom	<b>CGMP Considerations for Cell Therapy Products Under IND</b> Laurie Norwood, MSc OCBQ, CBER, FDA
		<b>Environmental Monitoring Approaches in Cell Therapy Product Manufacturing</b> Angela Ondo, MT(ASCP) Johns Hopkins Medicine
		<b>Media Fill Evaluations in Cellular Therapy Product Manufacturing: Three Possible Approaches</b> Doug Padley, MT(ASCP) Mayo Foundation
		<b>Cleaning and Sanitization Strategies for Clinical Cell Therapies</b> Robert Preti, PhD Progenitor Cell Therapy, LLC
2:45 — 3:15 pm	Coffee Break	Crystal Ballroom Foyer

3:15 — 4:30 pm	Facility & Operational Issues for Cord Blood Banks  Crystal Ballroom	<p><b>Panel Co-Chairs:</b> Lynn O'Donnell, PhD James Cancer Hospital &amp; Research Institute</p> <p>Ellen Areman, MS, SBB(ASCP) Biologics Consulting Group, Inc.</p> <p><b>Cord Blood Processing Facility Challenges — what does cGMP mean?</b> Mary Malarkey, BSc Director, OCBQ, CBER, FDA</p> <p><b>GMP Challenges for Cord Blood Banks</b> Donna Regan, MT(ASCP)SBB Cardinal Glennon Children's Medical Center</p> <p><b>Facility Issues of a Large Mult-National Cord Blood Bank</b> Robert Chow, MD StemCyte, Inc.</p>
4:30 — 5:30 pm	Combination Products  Crystal Ballroom	<p><b>Panel Chair:</b> John McMannis, PhD MD Anderson Cancer Center</p> <p><b>Regulation of Combination Products</b> Kimberly Benton, PhD OCTGT, CBER, FDA</p> <p><b>Development of an Autologous Neo-bladder Construct</b> Tim Bertram, DVM, PhD Tengion Inc.</p> <p><b>Validation of a Combination Product for Treating Cardiac Disease</b> John McMannis, PhD MD Anderson Cancer Center</p>



Time	Topic	Speakers
7:00 — 8:00am	Registration & Breakfast	Crystal Ballroom Foyer
<b>Product Characterization &amp; Stability</b>		
8:00 — 8:30 am	Assay Validation  Crystal Ballroom	<p><b>Overview of Assay Validation</b> Thomas Finn, PhD OCTGT, FDA</p>
8:30 — 9:45 am	Microbiological Testing  Crystal Ballroom	<p><b>Panel Chair:</b> Elizabeth J Read, MD Blood Systems Research Institute</p> <p><b>Sterility testing of 361 and early phase 351 cell therapy products in an academic center</b> Hanh Khuu, MD National Institute of Health</p> <p><b>Validation of the BacT/Alert as an alternative sterility test for Dendreon's autologous cell therapy product</b> Timothy Wood, BSc Dendreon Corporation</p> <p><b>Microbial testing of 351 HCT/Ps intended for commercialization</b> Miguel Nogueras, BS, MT BioReliance</p>
9:45 — 10:00 am	Coffee Break	Crystal Ballroom Foyer
10:00 — 11:30 am	Potency Assays  Crystal Ballroom	<p><b>Panel Chair:</b> Carolyn Keever-Taylor, PhD Medical College of Wisconsin</p>

11:30 — 12:30 pm	Product Stability  Crystal Ballroom	<p><b>Panel Chair:</b> Janice Davis-Sproul, MAS, MT(ASCP)SBB Johns Hopkins Medicine</p> <p><b>Introduction: Stability Programs</b> <b>Development of a Stability Program for a Cord Blood Bank</b> Safa Karandish, MT(ASCP) MD Anderson Cancer Center</p> <p><b>Short-Term Stability: Validation of NK Cell Activation During Long-Distance Shipping</b> David McKenna, Jr., MD University of Minnesota Medical Center</p> <p><b>Development of a Stability Program in support of a BLA for a Stem Cell Therapeutic</b> Michelle LeRoux Williams, PhD Osiris Therapeutics, Inc.</p>
12:30 — 12:40 pm	Wrap up Crystal Ballroom	Janice Davis-Sproul, MAS, MT(ASCP)SBB Johns Hopkins Medicine

**Potency assay validation for Auto-CD34+ HPC**  
Carolyn Keever-Taylor, PhD  
Medical College of Wisconsin

**Product potency in cord blood products**  
Donna Regan, MT(ASCP)SBB  
Cardinal Glennon Children's Hospital

**Development of a Potency Assay for GVAX Prostate Cancer Cellular Immunotherapy**  
Shirley Clift  
Cell Genesys, Inc.

**Potency of multi-virus specific CTL from allogeneic donors**  
Ann Leen, PhD  
Baylor College of Medicine

## Organizing Committee

### CO-CHAIRS

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

Elizabeth J. Read, MD  
Blood Systems Research Institute

### COMMITTEE MEMBERS

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