

**Sixth Annual Somatic Cell Therapy Symposium
September 25-27, 2006**

Monday, September 25, 2006

7:30 – 8:00 am	Registration & Breakfast
8:00 – 8:15 am	Welcome
8:15 – 8:45 am	<p>Session 1: FDA Perspective</p> <p>Celia Witten, PhD, MD Director, Office of Cellular, Tissue & Gene Therapies (OCTGT) CBER, FDA Rockville, Maryland</p>
8:45 – 10:15am	<p>Session 2: Novel Therapies I</p> <p>Moderators: Linda Kelley, PhD University of Utah Salt Lake City, Utah</p> <p>Stephen Noga, PhD, MD Alvin & Lois Lapidus Cancer Center Baltimore, Maryland</p> <p>Mercy Quagraine, PhD OCTGT, DCGT Rockville, Maryland</p> <p><i>Skeletal Myeloblasts for Cardiac Disease</i> <i>Neural Cells for Degenerative Diseases</i> <i>Bio-engineered Corneal Surface Tissue for Corneal Repair</i></p>
10:15 – 10:30 am	Break
10:30 – 12:00 pm	<p>Session 3: Novel Therapies II</p> <p><i>Mesenchymal Stem Cells for Kidney Failure</i> <i>Pancreatic Islets</i> <i>Mesenchymal Stem Cells for Cardiac Disease</i></p>
12 – 12:30 pm	Lunch

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12:30 – 1:30 pm	Session 4: Reporting Events Moderators: Elizabeth J. Read, MD National Institutes of Health Bethesda, Maryland Ke Liu, PhD, MD OCTGT, DCEPT Rockville, Maryland <i>Scenario based panel discussion</i>
1:30 – 3:00 pm	Session 5: Release Testing I Moderators: Ellen Areman, MS, SBB(ASCP) Biologics Consulting Group Maryland Brenton McCright, PhD OCTGT,DCGT Rockville, Maryland <i>FDA Perspective</i> <i>Evaluating novel methods for endotoxin testing of cellular products – the PACT experience</i> <i>Sterility Testing: ‘Outside the box’ Alternate samples and methods</i> <i>Developing a potency assay for MSCs used to treat GvHD</i> <i>Developing a potency assay for cellular immunotherapy products</i>
3:00 – 3:15 pm	Break
3:15 – 4:45 pm	Session 6: Release Testing II-Practical Experiences Moderators: Shelly Heimfeld, PhD Fred Hutchinson Cancer Research Center Seattle, Washington Keith Wonnacott, PhD OCTGT,DCGT Bethesda, Maryland <i>HCT/P Product Release</i> <i>Pancreatic Islet Product Release</i> <i>Release Criteria for ALDHbr Cells</i>

6:00 – 7:30pm Somatic Cell Reception

**Sixth Annual Somatic Cell Therapy Symposium
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Tuesday, September 26, 2006

7:30 – 8:30 am	Corporate Sponsored Breakfast Sessions		
	BioLife Solutions Embassy/Patuxent	BioSpherix Diplomat/Ambassador	Progenitor Cell Therapy, LLC Judiciary Suite
8:50 – 9:00 am	Introduction		
9:00 – 10:30 am	<p align="center">Session 7: Facilities Issues for Somatic Cell Therapy Product Manufacture</p> <p align="center">Moderators: Douglas Padley, PhD Mayo Clinic Rochester, Minnesota</p> <p align="center">James Crim, BS OCBQ/DMPQ Rockville, Maryland</p> <p align="center"><i>FDA Expectations for Facilities (Overview)</i> <i>Facility Construction</i> <i>Retrofitting a Laboratory</i> <i>Designing a 'New' GMP Laboratory</i> <i>Facility requirements for a HCT/P vs an IND-product</i> <i>What can Media Fills do for you?</i></p>		
10:30 – 10:45 am	Break		
10:45 – 12:15 pm	<p align="center">Session 8: INDs 202</p> <p align="center">Moderators: John McMannis, PhD MD Anderson Cancer Center Houston, Texas</p> <p align="center">Donald Fink, PhD (CMC) OCTGT/DCGT Rockville, Maryland</p> <p align="center">Steven Hirschfeld, MD (Clinical) OCTGT/DCEPT Rockville, Maryland</p> <p align="center"><i>FDA perspective (CMC and Clinical)</i> <i>Industry perspective</i> <i>Somatic Cells</i> <i>Pancreatic Islets, Cord Blood</i> <i>Cardiac Therapies, Multi-center Trials</i></p>		

**Sixth Annual Somatic Cell Therapy Symposium
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12:15 – 1:15 pm	Lunch
1:15 – 2:45 pm	<p>Session 9: Donor Issues</p> <p>Moderators: Zbigniew Szczepiorkowski, MD, PhD Dartmouth-Hitchcock Medical Center Lebanon, New Hampshire</p> <p>Melissa Greenwald, MD OCTGT/DHT Rockville, Maryland</p> <p><i>Scenario based panel discussion</i></p>
2:45 – 3:00 pm	Break
3:00 – 4:30 pm	<p>Session 10: Cord Blood – Future Directions</p> <p>Moderators: Liana Harvath National Heart, Lung, and Blood Institute Bethesda, Maryland</p> <p>Ellen Lazarus, MD OCTGT/DHT Rockville, Maryland</p> <p><i>FDA Update on Cord Blood Banking Regulations Optimizing results of Cord Blood Transplants Ex vivo expanded cord blood HRSA National Cord Blood Bank Program</i></p>
4:30 – 5:00 pm	Wrap Up
<p>AABB Reception 5:00 – 7:00 pm</p>	

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Wednesday, September 27, 2006

7:30 – 8:30 am	Corporate Sponsored Breakfast Sessions		
	Pall Life Sciences Embassy/Patuxent	PharmaNet Diplomat/Ambassador	StemSoft Software Judiciary Suite
8:40 – 8:45 am	Introduction		
8:45 – 9:15 am	Working Group Presentations		
9:15 – 10:45 am	<p>Session 11: Professional Certification Models, Challenges, Maintenance, Costs, International recognition</p> <p>Moderator: Kathy Loper, MHS, MT(ASCP) AABB Bethesda, Maryland</p> <p>AATB Professional Certification ASCP Certification Regulatory Affairs Professionals (RAPS) Certification Program New York State Regulation of Tissue Banks Training Programs AABB Model: A Certificate Program</p>		
10:45 – 11:00 am	Break		
11:00 – 12:30 pm	<p>Session 12: The Quest for Compatibility: AABB, AATB, CAP, FACT, JACIE, NETCORD, NMDP</p> <p>Moderators:</p> <p>Janice Davis-Sproul, MAS, MT(ASCP)SBB Johns Hopkins Hospital Baltimore, Maryland</p> <p>Jennifer Catalano, PhD OCTGT/DCGT Rockville, Maryland</p> <p>Overview of the ICH Process</p> <p>Overview of International Regulations and Standards for Cell Therapy Accreditation Challenges & Solutions</p>		
12:30 – 12:45 pm	Wrap Up		