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

### Monday, September 25, 2006

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

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*Hyatt Regency Bethesda · Maryland, USA*
## Schedule of Events

### 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

Scenario based panel discussion

### 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

**FDA Perspective**  
Evaluating novel methods for endotoxin testing of cellular products  
- the PACT experience  
Sterility Testing: ‘Outside the box’ Alternate samples and methods  
Developing a potency assay for MSCs used to treat GvHD  
Developing a potency assay for cellular immunotherapy products

### 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

**HCT/P Product Release**  
Pancreatic Islet Product Release  
Release Criteria for ALDHbr Cells

### 6:00 – 7:30 pm

Somatic Cell Reception
<table>
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<tr>
<th>Time</th>
<th>Corporate Sponsored Breakfast Sessions</th>
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| 7:30 – 8:30 am | BioLife Solutions  
Embassy/ Patuxent  
BioSpherix  
Diplomat/ Ambassador  
Progenitor Cell Therapy, LLC  
Judiciary Suite |
| 8:50 – 9:00 am | Introduction                                                                                           |
| 9:00 – 10:30 am | Session 7: Facilities Issues for Somatic Cell Therapy Product Manufacture  
**Moderators:**  
Douglas Padley, PhD  
Mayo Clinic  
Rochester, Minnesota  
James Crim, BS  
OCBQ/ DMPQ  
Rockville, Maryland  
**FDA Expectations for Facilities (Overview)**  
**Facility Construction**  
**Retrofitting a Laboratory**  
**Designing a ‘New’ GMP Laboratory**  
**Facility requirements for a HCT/P vs an IND-product**  
**What can Media Fills do for you?** |
| 10:30 – 10:45 am | Break                                                                                                   |
| 10:45 – 12:15 pm | Session 8: INDs 202  
**Moderators:**  
John McMannis, PhD  
MD Anderson Cancer Center  
Houston, Texas  
Donald Fink, PhD (CMC)  
OCTGT/ DCGT  
Rockville, Maryland  
Steven Hirschfeld, MD (Clinical)  
OCTGT/ DCEPT  
Rockville, Maryland  
**FDA perspective (CMC and Clinical)**  
**Industry perspective**  
**Somatic Cells**  
**Pancreatic Islets, Cord Blood**  
**Cardiac Therapies, Multi-center Trials** |
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<tr>
<td>12:15 – 1:15 pm</td>
<td>Lunch</td>
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| 1:15 – 2:45 pm | **Session 9:** Donor Issues  
**Moderators:**  
Zbigniew Szczepiorkowski, MD, PhD  
Dartmouth-Hitchcock Medical Center  
Lebanon, New Hampshire  
Melissa Greenwald, MD  
OCTGT/ DHT  
Rockville, Maryland  
Scenario based panel discussion |
| 2:45 – 3:00 pm | Break                    |
| 3:00 – 4:30 pm | **Session 10:** Cord Blood – Future Directions  
**Moderators:**  
Liana Harvath  
National Heart, Lung, and Blood Institute  
Bethesda, Maryland  
Ellen Lazarus, MD  
OCTGT/ DHT  
Rockville, Maryland  
**FDA Update on Cord Blood Banking Regulations**  
**Optimizing results of Cord Blood Transplants**  
**Ex vivo expanded cord blood**  
**HRSA National Cord Blood Bank Program** |
| 4:30 – 5:00 pm | Wrap Up                   |
|               | **AABB Reception**  
5:00 – 7:00 pm |
### Corporate Sponsored Breakfast Sessions

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<tr>
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<td><strong>StemSoft Software</strong></td>
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<td>8:40 – 8:45 am</td>
<td><strong>Introduction</strong></td>
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<td>8:45 – 9:15 am</td>
<td><strong>Working Group Presentations</strong></td>
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<td>9:15 – 10:45 am</td>
<td><strong>Session 11</strong>: Professional Certification</td>
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<td>Models, Challenges, Maintenance, Costs, International recognition</td>
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<td><strong>Moderator:</strong> K. Loper, MHS, MT(ASCP)</td>
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<td>AABB</td>
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<td>Bethesda, Maryland</td>
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<td><strong>AATB Professional Certification</strong></td>
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<td>Regulatory Affairs Professionals (RAPS) Certification Program</td>
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<td>New York State Regulation of Tissue Banks</td>
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<td>Training Programs</td>
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<td>AABB Model: A Certificate Program</td>
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<td>11:00 – 12:30 pm</td>
<td><strong>Session 12</strong>: The Quest for Compatibility: AAB, AATB, CAP, FACT, JACIE, NETCORD, NMDP</td>
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<td><strong>Moderators:</strong></td>
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<td>Janice Davis-Sproul, MAS, MT(ASCP)SBB</td>
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<td>Johns Hopkins Hospital</td>
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<td>Jennifer Catalano, PhD</td>
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<td><strong>Overview of the ICH Process</strong></td>
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<td><strong>Overview of International Regulations and Standards for Cell Therapy</strong></td>
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<td><strong>Accreditation Challenges &amp; Solutions</strong></td>
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