Unparalleled Commitment
To Your Cell Therapy Manufacturing Needs

One of the largest contract manufacturers of biologics in the world, Lonza is the global leader in cell therapy manufacturing. We deliver the technical expertise and manufacturing capabilities you need, with an unrivaled commitment to large-scale production:

— Extraordinary expertise and full service capabilities in cell isolation and cell therapy manufacturing, as well as tissue acquisition
— State-of-the-art facilities and infrastructure in the U.S. and Europe
— Compliance with ISO Class 7 (U.S. Class 10,000) and ISO Class 5 (EU Class B)

Lonza can take you through the entire life cycle of a product. Bring us your concept. We’ll scale up and optimize your process. Then we’ll provide manufacturing for your Phase 1 to commercial scale product. We can even use our established distribution infrastructure to deliver product to your clinical sites.

If you’re a lab with a big idea, a biotech firm, or pharmaceutical company looking for a long-term partner, contact Lonza today.

Visit our website at www.lonzabioscience.com/celltherapy or call 301-898-7025, ext. 2510.
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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- BioLife Solutions
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- Invitrogen
- StemLab
- Dynal

ISCT also acknowledges the following supporters of the meeting:

**CO-SPONSORS**

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**PROGRAM**

**Wednesday, September 26, 2007**

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<th>Time</th>
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<th>Speakers</th>
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<td>7:00 — 8:30 am</td>
<td>Registration &amp; Breakfast</td>
<td>Breakfast served in Cabinet Foyer</td>
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| 7:30 — 8:30 am | Corporate Sponsored Breakfast Sessions    | Progenitor Cell Therapy
Discussion of Impact of FDA
Guidance on Cell Selection
Devices for Point of Care
Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells

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Cabinet Suite
Judiciary Suite
Old Georgetown Room

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| 8:40 — 8:50 am | Welcome                                   | Elizabeth J Read, MD
Blood Systems Research Institute                                             |
| 8:50 — 10:20 am | Introduction to the Regulation of Cellular Therapy | CBER/OCGT Update
Session Chair: Elizabeth J Read, MD
Blood Systems Research Institute
Crystal Ballroom
Celia Witten, MD, PhD
Director, OCTGT, CBER, FDA
Ellen Lazarus, MD
OCTGT, CBER, FDA
Regulatory Perspective on the Development of Manufacturing Processes
Keith Wonnacott, PhD
OCTGT, CBER, FDA

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<td>10:20 — 10:45 am</td>
<td>Coffee Break</td>
<td>Crystal Ballroom Foyer</td>
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| 10:45 — 12:15 pm | Donor Issues                              | Panel Chair: David McKenna, Jr., MD
University of Minnesota Medical Center
Crystal Ballroom
Update on Donor Issues
Melissa Greenwald, MD
OCTGT, CBER, FDA
Ruth Solomon, MD
OCTGT, CBER, FDA
Donor Screening Challenges for Cord Blood Products
John Miller, MD
National Marrow Donor Program
Tissue Donor Testing and Screening Issues
Scott Brubaker, CTBS
American Association of Tissue Banks
Decision Analysis for Screening of HCT/P Donors
Brian Custer, PhD, MPH
Blood Systems Research Institute

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<td>12:15 — 1:45 pm</td>
<td>Lunch &amp; Working Group Summaries</td>
<td>Crystal Ballroom</td>
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|              | Chair:                                     | Shelly Heimfeld, PhD
Facility Sanitation Devices
Homologous Use
Microbiological Testing
### Novel Therapies I

**Panel Chair:**
- Bruce Levine, PhD
- University of Pennsylvania

**Crystal Ballroom**

**Regulatory Challenges for The Development of Allogeneic Mesenchymal Stem Cell Product**
- Rod Morrey, PhD
- Osiris Therapeutics, Inc.

**Application of Zinc Finger Nuclease Gene Disruption Technology to Manufacture Genetically Modified T cells for HIV Therapy**
- Bruce Levine, PhD
- University of Pennsylvania

**PEG Encapsulated Islets for the Treatment of Diabetes**
- Xiaojie Yu, PhD
- Novocell Inc.

# Use of Devices in Manufacturing Cell Therapy Products

**Panel Chair:**
- Ellen Areman, MS, SBB(ASCP)
- Biologics Consulting Group, Inc

**CBER Regulation of Devices for Cell Therapy**
- Richard McFarland, MD, PhD
- OCTGT, CBER, FDA

**IDE Submissions for Devices Used to Manufacture Cell Therapy Products**
- Janice Davis-Sproul, MAS, MT(ASCP)
- Johns Hopkins Medicine

**Use of Automated Separation Devices for Cord Blood Processing**
- Saba Karandish, MT(ASCP)
- MD Anderson Cancer Center

**Technical and Regulatory Considerations for Use of a Bioreactor in Clinical Cell Manufacturing Under an IND**
- Bruce Levine, PhD
- University of Pennsylvania

# Facility & Operational Issues for Cell Therapy Facilities

**Panel Chair:**
- Lynn O’Donnell, PhD
- Ohio State University, James Cancer Hospital

**CGMP Considerations for Cell Therapy Products Under IND**
- Laurie Norwood, MSc
- OCBQ, CBER, FDA

**Environmental Monitoring Approaches in Cell Therapy Product Manufacturing**
- Angela Ondo, MT(ASCP)
- Johns Hopkins Medicine

**Media Fill Evaluations in Cellular Therapy Product Manufacturing: Three Possible Approaches**
- Doug Padley, MT(ASCP)
- Mayo Foundation

**Cleaning and Sanitization Strategies for Clinical Cell Therapies**
- Robert Preti, PhD
- Progenitor Cell Therapy, LLC

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**Meeting Schedule**

- **9:00 — 10:00 am**
  - Coffee Break
  - Crystal Ballroom Foyer

- **10:00 — 10:30 am**
  - Novel Therapies I
  - Crystal Ballroom

- **10:30 — 12:00 pm**
  - Novel Therapies II
  - Crystal Ballroom

- **12:00 — 1:15 pm**
  - Lunch & Working Group Summaries
  - Crystal Ballroom

- **1:15 — 2:45 pm**
  - Facility & Operational Issues for Cell Therapy Facilities
  - Crystal Ballroom

- **2:45 — 3:15 pm**
  - Coffee Break
  - Crystal Ballroom Foyer

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**Schedule Highlights**

- **Registration & Breakfast**
  - Serviced in Cabinet Foyer

- **Corporate Sponsored Breakfast Sessions**
  - BioLife Solutions
  - Advanced Preservation Technologies: Improving Biopreservation Yield
  - GE Healthcare
  - Focusing on Regulatory Aspects in Setting Up a GMP Facility
  - CellGenix
  - Closed Systems for Cellular Therapy: Make It Your Starting Point

- **Use of Banked Cells in Manufacturing Cell Therapy Products**
  - Crystal Ballroom

- **Cell Banking: Issues and Guidance**
  - Brenton McCright, PhD
  - OCTGT, CBER, FDA
3:15 — 4:30 pm  Facility & Operational Issues for Cord Blood Banks
Crystal Ballroom
Panel Co-Chairs:
Lynn O’Donnell, PhD
James Cancer Hospital & Research Institute
Elen Areman, MS, SBB(ASCP)
Biologics Consulting Group, Inc.
Cord Blood Processing Facility Challenges — what does cGMP mean?
Mary Malaker, BSc
Director, OCBQ, CBER, FDA
GMP Challenges for Cord Blood Banks
Donna Regan, MT(ASCP)SBB
Cardinal Glennon Children’s Medical Center
Facility Issues of a Large Multinational Cord Blood Bank
Robert Chow, MD
StemCyte, Inc.

4:30 — 5:30 pm  Combination Products
Crystal Ballroom
Panel Chair:
John McMannis, PhD
MD Anderson Cancer Center
Regulation of Combination Products
Kimberly Benton, PhD
OCTGT, CBER, FDA
Development of an Autologous Neo-bladder Construct
Tim Bertram, DVM, PhD
Tengion Inc.
Validation of a Combination Product for Treating Cardiac Disease
John McMannis, PhD
MD Anderson Cancer Center

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

12:30 — 12:40 pm  Wrap up
Crystal Ballroom
Janice Davis-Sproul, MAS, MT(ASCP)SBB
Johns Hopkins Medicine

Friday, September 28, 2007

Time  Topic  Speakers
7:00 — 8:00am  Registration & Breakfast
Crystal Ballroom Foyer

Product Characterization & Stability
8:00 — 8:30 am  Assay Validation
Crystal Ballroom
Overview of Assay Validation
Thomas Finn, PhD
OCTGT, FDA

8:30 — 9:45 am  Microbiological Testing
Crystal Ballroom
Panel Chair:
Elizabeth J Read, MD
Blood Systems Research Institute
Sterility testing of 361 and early phase 351 cell therapy products in an academic center
Hanh Khuu, MD
National Institute of Health
Validation of the BacT/Alert as an alternative sterility test for Dendreon’s autologous cell therapy product
Timothy Wood, BSc
Dendreon Corporation
Microbial testing of 351 HCT/Ps intended for commercialization
Miguel Noqueras, BS, MT
BioReliance

9:45 — 10:00 am  Coffee Break
Crystal Ballroom Foyer

10:00 — 11:30 am  Potency Assays
Crystal Ballroom
Panel Chair:
Carolyn Keever-Taylor, PhD
Medical College of Wisconsin
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
Boyar College of Medicine

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Johns Hopkins Medicine
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