

# Cell & Tissue Bioprocessing

## Process Development and Production Issues

**8th Annual Meeting**

September 22-25, 2003

Memphis, Tennessee

### Topics Include:

- Tissue and Cell Procurement
- Cell Expansion
- Cell Selection / Isolation
- Clinical Administration
- Safety Testing
- Implant Preparation
- Cryopreservation
- Storage & Stability
- Cell Processing / Transduction
- Assay & Media Development

As the biotech industry becomes more experienced and successful, more technically demanding therapeutic approaches are being attempted. In particular, there is an ever-increasing number of treatments entering clinical trials in which the product is a processed cell population or three-dimensional cellular matrix. These applications truly represent the "biotech frontier" as their unique processing requirements demand novel nutrient formulations, manufacturing techniques, assay methodologies, and regulatory perspectives.

Please join us as we discover the challenges and success stories of the organizations that are developing viable commercial products, and learn how they are making these novel treatments work in the clinic. The presentations will focus on the latest techniques for procurement, isolation, expansion, processing, maintenance and delivery of cell populations, while covering the latest trends in regulatory practices and facility design.

### Hotel Accommodations

The Peabody has offered a special rate of \$165 per night plus applicable sales tax. All reservations must be made directly with the hotel:

**The Peabody**  
**149 Union Avenue**  
**Memphis, TN 38103**  
**(901) 529-4000**

To receive the conference rate of \$165, you must reserve your room no later than August 24, 2003, and specify you will be attending the Cell & Tissue Bioprocessing Conference.

Sponsored by:



# Cell & Tissue BioProcessing

September 22 – 25, 2003

## Sunday, September 21

4:00-6:00 pm: *Registration, Welcome Reception, and Exhibit Set Up*

## Monday, September 22

7:00-8:00 am: *Registration and Continental Breakfast - Meeting Room Foyer*

8:00-8:30 am: **Introduction**  
Keith L. Carson - *Conference Chairman*

8:30-9:15 am: **Clinical Scale Production and Characterization of Antigen-Specific T Cells Directed Against the Hepatitis B Virus**  
David McMillen, Ph.D. – *CellExSys*

9:15-10:00 am: **Implementation of a Bioreactor-based Process for the GMP Manufacture of Autologous Xcellerated T Cells™**  
Stewart Craig, Ph.D. – *Xcyte Therapies, Inc.*

10:00-10:30 am: **Break - Exhibit Area**

10:30-11:15 am: **Cytopherapy As a Translational Laboratory - Bridging the Gap Between Manufacturing and Research**  
Shanta Sharma, Ph.D. – *Memorial Sloan Kettering Cancer Center*

11:15-12:00 noon: **Challenges for Multi-Product Academic Cell Processing Facilities**  
Adrian Gee, Ph.D. – *Baylor College of Medicine*

12:00-1:30 pm: *From the Grill Lunch* – **Exhibit Area**

1:30-2:15 pm: **Issues in Commercialization of Cell and Gene Therapies**  
Scott Burger, M.D. - *Advanced Cell & Gene Therapy, LLC.*

2:15-3:00 pm: **Questions and Answers for Multi-product Manufacturing of Cellular Medicines**  
Robert Preti, Ph.D. – *Progenitor Cell Therapy, L.L.C.*

3:00-3:30 pm: **Break - Exhibit Area**

3:30-4:15 pm: **Cell Therapies Based on Macrophages and Dendritic Cells**  
Andres McAllister, Ph.D. – *Immuno-Designed Molecules*

4:15-5:00 pm: **Development and Characterization of an Autologous Tumor Vaccine for Non Small Cell Lung Cancer**  
Flavia Borellini, Ph.D. – *Cell Genesys, Inc.*

5:00-5:45 pm: **Rapid, Intra-Operative, Density Gradient Free, MSC Isolation with the Magellan™ System**  
Jeffrey Marx, Ph.D. – *Medtronic, Inc.*

6:00-7:30 pm: *Beale Street Reception* - **Exhibit Area**

## Tuesday, September 23

7:30-8:30 am: *American Breakfast* - **Exhibit Area**

8:30-9:15 am: **Approaches to Accelerated Manufacturing of Biological Products**  
Mary Pat Moyer, Ph.D. – *INCELL Corporation, L.L.C.*

9:15-10:00 am: **U.S. Department of Health and Human Services (HHS) Regulations (45 CFR 46) What are the Regulations Regarding Human Tissue Research and Repositories, and Most Importantly, Do They Apply to Me?**  
Shirley Hicks - *OHRP*

10:00-10:30 am: **Break - Exhibit Area**

- 10:30-11:15 am: **Commercial GMP/GTP Bioprocess Manufacturing in Support of Early and Mid-stage Cell and Tissue Therapy Companies**  
Natika Calhoun – *Life Blood*
- 11:15-12:00 noon: **T Lymphocyte Engineering Ex vivo for Cancer and Infectious Disease**  
Bruce Levine, Ph.D. – *University of Pennsylvania*
- 12:00-5:00 pm: **Free Afternoon with Recommended Group Activities**
- 5:00-6:30 pm: **Happy Hour- Exhibit Area**

**Wednesday, September 24**

- 7:30-8:30 am: **Continental Breakfast - Exhibit Area**
- 8:30-10:00 am: **Technical Workshops I**
- 10:00-10:30 am: **Break - Exhibit Area**
- 10:30-12:00 noon: **Technical Workshops II**
- 12:00-1:30 pm: **Mexican Luncheon Buffet - Exhibit Area**
- 1:30-2:15 pm: **Slippery Slope: Acquisition and Processing of Adipose Tissue for Cellular Products**  
William Wilkison, Ph.D. – *GlaxoSmithKline*
- 2:15-3:00 pm: **A Comparative Study of Molecular Biomarkers Used to Detect Cellular/Genetic Damage in Tissue-Engineered Skin**  
Henry Rodriguez, Ph.D. – National Institutes of Standards & Technologies
- 3:00-3:30 pm: **Break – Exhibit Area (Exhibit Tear Down at 3:30 pm)**
- 3:30-4:15 pm: **Short and Long Term Storage Conditions for Cellular Products**  
John McMannis, Ph.D.- MD Anderson Cancer Center
- 4:15-5:00 pm: **Development of Anti-HIV Gene Therapy with Retroviral Vectors**  
Klaus Kuehlicke, Ph.D. – Eufets AG
- 6:00-9:00 pm: **Heartbreak Hotel Banquet**

**Thursday, September 25**

- 7:30-8:30 am: **Continental Breakfast – Exhibit Area**
- 8:30-9:15 am: **Automated Perfusion Culture System**  
Paul Kosnik, Ph.D. – *Tissue Genesis, Inc*
- 9:15-10:00 am: **Application of Q-PCR Assays for Residual DNA, Viral Clearance, and Endogenous Retrovirus Measurement**  
Audrey Chang, Ph.D. – *BioReliance Corporation*
- 10:00-10:30 am: **Break – Meeting Foyer**
- 10:30-11:15 am: **A Non-Viral Cell-Loading System Enabling Bioprocessing and Therapeutic Gene Delivery Applications**  
Joseph Fratantoni, M.D. – MaxCyte Inc.
- 11:15-12:00 noon: **Persistence and Vision from Product Concept to Commercialization**  
Nancy Drake – *Islet Technology, Inc*

*Due to circumstances beyond the control of the conference organizers, the speaker list is subject to change.*

**Participating Exhibitors Include:**

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|------------------------------------|--------------------------|-----------------------------|
| ◆ Amersham Biosciences Corporation | ◆ Corning, Inc.          | ◆ MDS Pharma Services       |
| ◆ Biomedical Resources Intl        | ◆ Invitrogen Corporation | ◆ Serologicals Corporation  |
| ◆ Q-One Biotech Inc.               | ◆ Pall Life Sciences     | ◆ Life Blood                |
| ◆ SeraCare Life Sciences, Inc.     | ◆ JRH Biosciences        | ◆ Cryonix, Inc.             |
| ◆ Spectrum Laboratories, Inc.      | ◆ Beckman Coulter, Inc.  | ◆ Aastrom Biosciences, Inc. |
| ◆ BioReliance Corporation          | ◆ AirNet Express         |                             |