

# Cell & Tissue BioProcessing

Process Development and Production Issues for Cellular Therapy & Tissue Engineering

## 4th Annual Meeting

September 26-29, 1999

Ramada Plaza Hotel

Alexandria, Virginia

## Program

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### Sunday, September 26

10:00-1:00 pm:

**Registration and Exhibit Set-Up**

1:00-1:30 pm:

**Introduction**

Keith L. Carson - *Conference Chairman*

1:30-2:15 pm:

**In-Process and Release Testing Requirements for Immunotherapeutic Products**

Madhusudan Peshwa, Ph.D. - *Dendreon Corporation*

2:15-3:00 pm:

**Development of a Selectively Depleted Bone Marrow Graft for Malignant Hematological Diseases**

Patricia Whelton - *Chimeric Therapies, Inc.*

3:00-3:30 pm:

**Break - Exhibit Area**

3:30-4:15 pm:

**Extended Serial Passaging of Mammalian Neural Stem Cells in Suspension Bioreactors**

Leo A. Behie, Ph.D. - *University of Calgary*

4:15-5:00 pm:

**Cell Processing in a Cancer Treatment Network**

Phillip B. Maples, Ph.D. - *U.S. Oncology, Inc.*

5:00-5:45 pm:

**Introducing the US Pharmacopeia's Draft Chapter on Cell & Gene Therapy Products**

Sally Seaver, Ph.D. - *U.S. Pharmacopeia*

6:00-8:00 pm:

**Mixer - Exhibit Area**

### Monday, September 27

7:30-8:30 am:

**Continental Breakfast - Exhibit Area**

8:30-9:15 am:

**Beta-Site Autologous Vaccine Production - Pitfalls & Practicalities**

Shirley M. Clift - *Cell Genesys, Inc.*

9:15-10:00 am:

**Clinical Manufacturing for Cell Therapy Products - What are the Issues?**

William R. Tolbert, Ph.D. - *W.R. Tolbert & Associates, LLC*

10:00-10:30 am:

**Break - Exhibit Area**

10:30-11:15 am:

**Delivery of Therapeutic Proteins from Organized Tissue Engineered Products**

Herman H. Vanderburgh, Ph.D. - *Cell Based Delivery, Inc.*

11:15-12:00 noon:

**Development of an Antibody-Coated High-Density Microparticle (HDM) System for Capture of Target Cells from Large Scale Apheresis Products**

Rod Monroy, Ph.D. - *Eligix, Inc.*

- 12:00-1:00 pm: **Lunch - Exhibit Area**
- 1:00-1:30 pm: **Technology Workshops**
- 1:30-2:15 pm: **The Impact of FAHCT Accreditation on the Transplantation Program**  
Phyllis I. Warkentin, M.D. - *Foundation for the Accreditation of Hematopoietic Cell Therapy*
- 2:15-3:00 pm: **Tissue Engineered Biologically Active Wound Dressing: Process, Structure, and Characterization of Composite Cultured Skin**  
Nitya G. Ray, Ph.D. - *Ortec International, Inc.*
- 3:00-3:30 pm: **Break - Exhibit Area**
- 3:30-4:15 pm: **Core Technologies for Tissue Engineering**  
Robert M. Nerem, Ph.D. - *Georgia Institute of Technology*
- 4:15-5:00 pm: **Optimization of a Cell Expansion Process for Mesenchymal Stem Cell Products of Variable Dose**  
Janice Davis-Sproul - *Osiris Therapeutics, Inc.*
- 6:00-8:00 pm: **The Old Town Reception - Exhibit Area**

**Tuesday, September 28**

- 7:30-8:30 am: **Continental Breakfast - Exhibit Area**
- 8:30-9:15 am: **The Quality Assurance of Cell & Tissue Procurement**  
Cynthia Entstrasser - *Genzyme Tissue Repair*
- 9:15-10:00 am: **Safety Concerns & Practical Solutions for Somatic Cell Therapeutic Products**  
Mio Sam Lao, Ph.D. - *MDS Panlabs Biosafety, Inc.*
- 10:00-10:30 am: **Break - Exhibit Area**
- 11:15-12:00 noon: **Manufacturing a Cell-Based Gene Therapy Product in a Pharmaceutical Production Environment**  
Thomas Leemhuis, Ph.D. - *Systemix, Inc.*
- 6:00-7:30 pm: **Conference Banquet - Union Street Public House**

**Wednesday, September 29**

- 7:30-8:30 am: **Continental Breakfast - Exhibit Area**
- 8:30-9:15 am: **Clinical Cell Processing for Immunotherapy**  
Dennis Gastineau, M.D. - *Mayo Clinic*
- 9:15-10:00 am: **A Matrix System for Hematopoietic Stem Cell Engineering**  
Todd Upton, Ph.D. - *Cytomatrix*
- 10:00-10:30 am: **Break - Exhibit Area**
- 10:30-11:15 am: **Cell Processing in an Academic Hospital-Based Facility**  
Elizabeth J. Read, M.D. - *National Institutes of Health Clinical Center*
- 11:15-12:00 noon: **Quality Control Issues and Regulatory Perspective for Xenogeneic Cell Based Therapies**  
Zorina Pitkin - *Circe Biomedical*
- 12:00-1:00 pm: **Lunch - Exhibit Area**
- 1:00-1:30 pm: **Technology Workshops**
- 1:30-2:15 pm: **Implementation of cGMP in a Gene Therapy Laboratory**  
Donna Rill - *Baylor College of Medicine, Center for Gene Therapy*
- 2:15-3:00 pm: **cGMP Cell Engineering for Clinical Therapies**  
Scott R. Burger, M.D. - *University of Minnesota, Somatic Cell Therapy Laboratories*
- 3:00-3:30 pm: **Break - Foyer**
- 3:30-5:00 pm: **Panel Discussion - Obstacles, Trends, Precedent, and Issues for Next Year**

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## List of Exhibitors

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Beckman Coulter  
Corning Labglass  
Nova Biomedicals  
Composite Rotor  
Irvine Scientific

Sigma Aldrich  
JRH BioSciences  
Bellco Glass  
Pall Corporation (Sponsors)  
Terracell