

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

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**

List of Exhibitors

Beckman Coulter
Corning Labglass
Nova Biomedicals
Composite Rotor
Irvine Scientific

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