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Austin, Texas, USA



# Cell and Tissue BioProcessing

October 29-31, 2007

## Cellular Products for Vaccines, Therapies and Tissue Regeneration

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.

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 products entering clinical trials that are processed cell populations or three-dimensional cellular matrixes. These applications truly represent the "biotech frontier" because their unique processing requirements demand novel nutrient formulations, manufacturing techniques, assay methodologies, and regulatory perspectives.

### Conference Co-Chairs

James Bender Ph.D. - IDM Pharma, Inc.

and

Phillip B. Maples, Ph.D. - Gradalis, Inc.

#### Topics:

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





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## Cellular Products for Vaccines, Therapies and Tissue Regeneration

### SUNDAY, OCTOBER 28, 2007

4:00-6:00 pm **Registration and Welcome Reception**

### MONDAY, OCTOBER 29, 2007

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

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

8:30-9:15 am **Encapsulated Cell Technology: Sustained Release Systems for Delivery of Proteins and Peptides**  
Konrad Kauper - Neurotech USA

9:15-10:00 am **Challenges of Building a Cryopreservation Bridge Between Manufacturing and Administration of a Viable Cell Product**  
David Frey - Cell Genesys, Inc.

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

10:30-11:15 am **Dendritic Cell Vaccine Production Facility: From Design to Operation**  
Nicolas Taquet - Baylor Institute for Immunology Research

11:15-Noon **Scaling up T cell Processing from a Phase I Clinical Trial to a Phase II Clinical Trial**  
Reuben Cohen - VIRxSYS Corporation

Noon-1:30 pm **Lunch and Poster Session - Exhibit Area**

1:30-2:15 pm **Development of Cell Therapy Products: FDA Perspective**  
Kimberly Benton, Ph.D. - FDA CBER

2:15-3:00 pm **A Novel Patient-Specific Cancer Vaccine Approach Based on Genetically Altered Tumor Immune Profile and Xenograft Tumor Expansion**  
Phillip Maples, Ph.D. - Gradalis, Inc.

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

3:30-4:15 pm **Bioprocess Implementation for Manufacture of Patient-Specific Cell Therapy Products**  
Brian Hampson - Aastrom Biosciences, Inc.

4:15-5:00 pm **Individualized Therapies in Oncology: From Man to Mice and Back**  
Craig Webb, Ph.D. - Van Andel Research Institute

5:00-5:45 pm **Mining The Placenta a Rich Source of Stem Cells And Natural Biomaterials**  
Mohammad Heidarani, Ph.D. - Celgene Cellular Therapeutics

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

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## **TUESDAY, OCTOBER 30, 2007**

- 8:00-8:30 am **American Breakfast - Exhibit Area**
- 8:30-9:15 am **Multi-Epitope Peptide Vaccines for Cancer: Dendritic Cells vs Conventional Adjuvants**  
James Bender, Ph.D. - IDM Pharma, Inc.
- 9:15-10:00 am **Comprehensive Cancer Management from a Cellular Bioprocessing Perspective**  
Pat Lawman, Ph.D. - Morphogenesis, Inc.
- 10:00-10:30 am **Break - Exhibit Area**
- 10:30-11:15 am **Cryopreservation of Cellular Tissue Engineered Construct Models**  
Kelvin Brockbank, Ph.D. - Cell and Tissue Systems, Inc.
- 11:15-Noon **Unique Challenges in Manufacturing and Commercializing an Autologous Cancer Immunotherapeutic**  
Stephen Monks, Ph.D. - Antigenics, Inc.
- 12:00-12:45 pm **Manufacturing for Commercialization**  
Brian Newsom - Opexa Therapeutics
- 12:45-6:00 pm **Free Afternoon with Recommended Group Activities**
- 6:00-9:00 pm **Happy Hour on your own on Sixth Street**

## **WEDNESDAY, OCTOBER 31, 2007**

- 7:30-8:30 am **Breakfast - Exhibit Area**
- 8:30-10:00 am **Technical Workshops I**
- 10:00-10:30 am **Break - Exhibit Area**
- 10:30-11:30 am **Technical Workshops II**
- Noon-1:30 pm **Lunch and Poster Session - Exhibit Area**
- 1:30-2:15 pm **Manufacturing Patient Specific Therapies: Strategic, Regulatory, and Scale-up Issues**  
R. Barry Holtz, Ph.D. - Holtz Biopharma Consultants
- 2:15-3:00 pm **Dendritic Cells For Active Immunotherapy: Optimizing Design And Manufacture In Order To Develop Commercially And Clinically Viable Products**  
Fred Miesowicz, Ph.D. - Argos Therapeutics
- 3:00-3:30 pm **Break - Exhibit Area**
- 3:30-4:15 pm **Why Your Mother Cares About the Future of Cell Therapy**  
Ron Jankowski, Ph.D. - Cook Myosite Inc.
- 4:15-5:00 pm **Automated Adipose-Derived Stem Cell Isolation at Point of Care**  
Paul Kosnik, Ph.D. - Tissue Genesis, Inc.
- 5:00-5:45 pm **Developing Monographs and USP Chapters for Cell Therapy Products**  
William Tente - USP Cell, Gene, and Tissue Therapies Expert Committee