

# Raw Materials & Contract Services

for Mammalian Cell Products

## 1st Annual Meeting

May 19-21, 1999

Marriott Pavilion Hotel

St. Louis, Missouri

## Program

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### Wednesday, May 19

- 7:00-8:00 am: **Continental Breakfast - Meeting Room Foyer**
- 8:00-8:30 am: **Introduction**  
Keith L. Carson - Conference Chairman
- 8:30-9:15 am: **Raw Materials - An Integrated Approach from Development to Manufacturing**  
Patricia Dennis, Ph.D. - *Biogen, Inc.*
- 9:15-10:00 am: **Life in the Middle: Process Development Efforts and Raw Material Selection**  
Nancy Connelly - *Schering-Plough Research Institute*
- 10:00-10:30 am: **Break - Exhibit Area**
- 10:30-11:15 am: **Raw Materials & Components in Bioprocessing: Enhancing Quality, Minimizing Risk, and Reducing Cost**  
Kripa Ram, Ph.D. - *SmithKline Beecham*
- 11:15-12:00 noon: **An Approach to Raw Material Quality for Early Phase Clinical Products**  
Susan Wade - *Cell Genesys, Inc.*
- 12:00-1:30 pm: **Lunch - Exhibit Area**
- 1:30-2:15 pm: **Raw Material Selection for Gene Delivery Vehicles**  
Maureen Costello, Ph.D. - *Copernicus Gene Systems, Inc.*
- 2:15-3:00 pm: **Raw Material Control for Gene and Cell Therapy**  
Steven S. Kuwahara, Ph.D. - *SyStemix, Inc.*
- 3:00-3:30 pm: **Break - Exhibit Area**
- 3:30-4:15 pm: **Lessons Learned in the Quality Control of Raw Materials for the Production of Gene Therapy Vectors**  
Charles Smith - *Targeted Genetics Corp.*
- 4:15-5:00 pm: **Developing Standards for Raw Materials in Xenotransplantation**  
Barbara Potts, Ph.D. - *University of Minnesota*
- 6:00-8:00 pm: **Riverfront Reception - Exhibit Area**

### Thursday, May 20:

- 7:30-8:30 am: **Continental Breakfast - Exhibit Area**
- 8:30-9:15 am: **Adventitious Agents Associated with Animal and Human Derived Raw Materials**  
Marshall Dinowitz, Ph.D. - *Genentech, Inc.*
- 9:15-10:00 am: **Replacing Animal-Derived Proteins in Raw Materials**  
Lokesh Bhattacharyya, Ph.D. - *Merck & Company*

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

10:30-11:15 am: **Characterization of Bovine-Derived and Vegetable-Derived Polysorbate-80**  
Thomas Patapoff, Ph.D. - *Genentech, Inc.*

11:15-12:00 noon: **Bovine Serum Albumin: A Complex Multi-Faceted Media Component**  
Sara Whitaker - *Centocor, Inc.*

12:45 pm: **Board Bus for Tours - Hotel Lobby (Box Lunch Provided)**

1:00-1:30 pm: **Guided Tour of St. Louis**

1:30-4:00 pm: **cGMP Facility Tour - Sigma-Aldrich Fine Chemicals**

6:00-7:30 pm: **Reception - Hosted by Sigma-Aldrich Fine Chemicals**

**Friday, May 21**

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

8:30-10:00 am: **Technology Workshop**

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

10:30 - 12:00 noon: **Panel Discussion**

1:30-2:15 pm: **Report Values for Out-Of-Specification Test Results**  
Lynn Torbeck - *Torbeck and Associates*

2:15-3:00 pm: **Managing Contract Manufacturing Services**  
David C. Dlesk - *Biogen, Inc.*

3:00-3:30 pm: **Break - Exhibit Area (Exhibit Tear Down at 3:30 pm)**

3:30-4:15 pm: **Understanding Key Issues in Biopharmaceutical Materials Supply Contracts**  
Gary E. Gamerman - *Heller Ehrman White & McAuliffe*

4:15-5:00 pm: **Elimination of Bovine Raw Materials from Human Viral Vaccine Production**  
Ming Bao Zhang, Ph.D. - *Wyeth-Lederle Vaccines & Pediatrics*