

Raw Materials & Contract Services for Mammalian Cell Products

Sponsored by:



2nd Annual Meeting

June 11-13, 2000

The Radisson Hotel Clayton

St. Louis, Missouri

Program

Sunday, June 11

- 8:00-10:00 am: **Registration - Meeting Room Foyer**
- 10:00-10:30 am: **Introduction**
Keith L. Carson - Conference Chairman
- 10:30-11:15 am: **A Novel Approach to the Development of ID Tests for Resins and Growth Media**
Nataliya Afonina - *Merck Research Laboratories*
- 11:15-12:00 noon: **Perspectives on Assuring the Quality of Materials and Reagents Used by cGMP Analytical Laboratories**
Nadine M. Ritter, Ph.D. - *BioReliance*
- 12:00-1:30 pm: **Lunch - Exhibit Area**
- 1:30-2:15 pm: **Manufacturing Issues Related to a Recombinant Subunit Vaccine**
Robert Repetto - *Wyeth-Lederle Pediatrics & Vaccines*
- 2:15-3:00 pm: **Chromatography Media as Raw Materials: QA and Production Issues**
Lisa Gonzales - *Amersham Pharmacia Biotech*
- 3:00-3:30 pm: **Break - Exhibit Area**
- 3:30-4:15 pm: **Management Can Accelerate the Progress of Biologics Through the Clinical Trial Process**
Simon J Y Saxby - *KS BioMedix Ltd.*
- 4:15-5:00 pm: **Starting a Raw Materials Program for Clinical Biotech Manufacturing**
Tina Young - *BioScience Contract Production Corp.*
- 5:30-7:00 pm: **The Home Run Reception - Exhibit Area**

Monday, June 12

- 7:30-8:30 am: **Continental Breakfast - Exhibit Area**
- 8:30-9:15 am: **Managing Specification Change for Raw Material Release by Quality Assurance**
Maureen A. Costello, Ph.D. - *Costello Associates*
- 9:15-10:00 am: **Raw Material Concerns in the Development of Vascugel**
Deborah J. Deane - *Reprogenesis*
- 10:00-10:30 am: **Break - Exhibit Area**

- 10:30-11:15 am: **Characterizing Clinical Trial Raw Materials for Use in Complex Products**
M. Shane Ray - *Encelle, Inc.*
- 11:15-12:00 noon: **Cell & Virus Banks as Raw Materials for Adenoviral Gene Therapy**
Beth Hutchins, Ph.D. - *Canji, Inc.*
- 12:30 pm: **Board Bus for Tour - Hotel Lobby (Box Lunch Provided)**
- 1:00-1:30 pm: **Guided Tour of St. Louis**
- 1:30-5:00 pm: **CGMP Facility Tour - Sigma-Aldrich Fine Chemicals**
- 5:00-7:30 pm: **Gala Reception - Park Avenue Art Gallery**
- Tuesday, June 13**
- 7:45-8:45 am: **Continental Breakfast - Exhibit Area**
- 8:45-9:15 am: **Technology Workshops**
- 9:15-10:00 am: **Optimization of Raw Materials for Porcine Hepatocyte-based Bioartificial Liver**
Santosh Raina - *Circe Biomedical, Inc.*
- 10:00-10:30 am: **Break - Exhibit Area**
- 10:30-11:15 am: **Emerging Concerns in Bovine Media and Supplements**
David Onions - *Q-ONE BIOTECH Inc.*
- 11:15-12:00 noon: **Experience With Upgrading Monoclonal Antibodies for Use in Cell Therapy**
Steven Ford, Ph.D. - *Chimeric Therapies*
- 1:30-2:15 pm: **Ensuring the Quality of Raw Materials**
Kevin Roberson - *Protein Design Labs*
- 2:15-3:00 pm: **Raw Material Control for Gene Therapy**
Steve Kuwahara, Ph.D. - *BioReliance*
- 3:00-3:30 pm: **Break - Exhibit Area**
- 3:30-5:00 pm: **Panel Discussion - QA/QC Perspective**
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List of Exhibitors

Serologicals Corp.	Sigma-Aldrich Fine Chemicals
Life Technologies	HyClone Laboratories, Inc.
Corning, Inc.	Applikon, Inc.
Amersham Pharmacia Biotech, Inc.	
