



Raw Materials & Contract Services

For Mammalian Cell Products

5th Annual Meeting

July 14-16, 2003

Newport Beach, California

Topics Include:

- Evaluating and Selecting Vendors
- Animal Sourced Materials
- Vendor Certification of Materials
- Media and Nutrient Supplements
- Regulatory and Legal Ramifications
- Outside Testing Services
- Managing Vendor Relationships
- Cell Lines and Tissue
- In-House Testing Requirements
- Contract Manufacturers and CROs
- Virtual Product Development
- Vendor's Role in Validation
- Biologics Process Development

As more biopharmaceutical products enter clinical trials and commercial production, it is becoming ever more challenging to guarantee the supply of critical raw materials and process support services. The sheer volume of some raw materials is testing the limits of many suppliers, even as more applications move toward the use of prepared and pre-sterilized materials. At the same time, advancements in analytical capabilities are raising the expectations within quality assurance programs that more data should be collected.

With so many new products entering clinical trials, no company will have the resources to handle all of its testing and development needs, or to produce all of its products at all manufacturing stages. Reliable vendors must be identified, evaluated, and managed to make sure they understand and can satisfy the volume, quality, documentation, and communication requirements of this rapidly growing industry.

Hotel Accommodations

The Four Seasons Newport Beach has offered a special rate of \$185 per night plus applicable sales tax. All reservations must be made directly with the hotel:

Four Seasons Newport Beach
690 Newport Center Drive
Newport Beach, CA 92660
(949) 759-0808

To receive the conference rate of \$185, you must reserve your room no later than June 27, 2003, and specify you will be attending the Raw Materials & Contract Services Conference.

Cancellation Policy

We will reimburse your registration fee less a \$100 cancellation charge if we receive a written cancellation no later than June 23, 2003. No refunds are available after this date.

Sponsored by:



Raw Materials & Contract Services

July 14 – 16, 2003

Sunday, July 13

4:00-6:00 pm: **Registration, Welcome Reception, and Exhibit Set Up**

Monday, July 14

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

8:00-8:30 am: **Introduction**

Keith L. Carson - *Conference Chairman*

8:30-9:15 am: **The Evolution of Inventory Replenishment Technologies**

Al Mottram- *Medarex, Inc.*

9:15-10:00 am: **Initiating a Raw Materials Program for Clinical Biotech Manufacturing**

Barry Friedman, Ph.D. – *Cambrex Biosciences Baltimore*

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

10:30-11:15 am: **Uses of Inductively Coupled Plasma (ICP) in the Biotech Industry**

Ila Patel – *Genentech, Inc.*

11:15-12:00 noon: **Managing Outside Testing Services**

Steve Swanson, Ph.D. – *Hanham Consulting*

12:00-1:30 pm: **Newport Beach Lunch - Exhibit Area**

1:30-2:15 pm: **Development of Animal Protein-Free and Chemically-Defined Media for NS0 Cell Culture Processes**

Jinyou Zhang, Ph.D. – *Merck & Company*

2:15-3:00 pm: **Fetal Bovine Serum: Traceability and Strategic Global Sourcing to Meet International Regulatory and Import Requirements, Including World Supply Trends.**

Paul Haffenden – *TerraCell*

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

3:30-4:15 pm: **Contractors, Suppliers, Quality System Audits, and Quality Agreements**

Maureen Costello, Ph.D. – *Seraphim Life Sciences, LLC*

4:15-5:00 pm: **Development and Validation of Assays for the Detection of Emerging Viruses Found in Common Raw Material Sources**

Garry Takle, Ph.D. – *AppTec Laboratory Services*

6:00-7:30 pm: **Cabo San Lucas Reception - Exhibit Area**

Tuesday, July 15

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

8:30-9:15 am: **Viable Cells: Clinical Raw Material for Cell & Gene Therapy**

Scott Burger, MD., Ph.D. – *Advanced Cell & Gene Therapy Consulting*

9:15-10:00 am: **Biopharmaceutical Contract Manufacturing at a Crossroads**

Roger Lias, Ph.D. – *KBI BioPharma, Inc.*

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

10:30-11:15 am: **Viral Safety: Strategic Approaches to Meeting Safety and Regulatory Requirements**

Marshall Dinowitz, Ph.D. – *Pacific BioDevelopment*

- 11:15-12:00 noon: **GMPs for Processing Clinical Trial Material**
Tom Thorpe – *Afton Scientific Corporation*
- 12:00-1:30 pm: **Newport Beach Lunch – Exhibit Area**
- 2:00 pm: **Board Bus for the Tour of the Irvine Scientific Manufacturing Facility**
- 7:00 – 10:00pm **Gala Dinner - Long Beach Aquarium**

Wednesday, July 16

- 7:30-8:30 am: **Continental Breakfast - Exhibit Area**
- 8:30-10:00 am: **Technical Workshops I**
- 10:00-10:30 am: **Break - Exhibit Area**
- 10:30-11:15 am: **Evaluation, Selection and Qualification of Raw Materials, Vendors and Manufacturers**
Yelena Fayvilevich – *Centocor, Inc.*
- 11:15-12:00 noon: **Manufacturing Recombinant Trypsin (TrypZean™) Expressed in Corn**
Cynthia Wooge, Ph.D. – *Sigma-Aldrich Fine Chemicals*
- 12:00-1:30 pm: **Mediterranean Countryside Lunch - Exhibit Area**
- 1:30-2:15 pm: **The CHO Family Tree**
Trish Benton – Nuvelo Inc.
- 2:15-3:00 pm: **Use of Microarray Analysis for the Development of Cell Culture Media**
Laurel M. Donahue, Ph.D.– *Sigma-Aldrich Fine Chemicals*
- 3:00-3:30 pm: **Break – Exhibit Area (Exhibit Tear Down at 3:30 pm)**
- 3:30-4:15 pm: **The Production of Biotherapeutics from Transgenic Porcine Sources**
Darcy Birse, Ph.D.- *TGN Biotech, Inc.*
- 4:15-5:00 pm: **Raw Materials Testing: Role of USP-NF Monographs and General Chapters**
Lokesh Bhattacharyya, Ph.D. – *U.S. Pharmacopeia*

Due to circumstances beyond the control of the conference organizers, the speaker list is subject to change.

Participating Exhibitors Include:

- | | | | |
|------------------------------------|------------------------------|--------------------------------|--------------------------------|
| ◆ Amersham Biosciences Corporation | ◆ HyClone Laboratories, Inc. | ◆ SeraCare Life Sciences, Inc. | ◆ Sigma-Aldrich Fine Chemicals |
| ◆ BioReliance Corporation | ◆ Invitrogen Corporation | ◆ Biovest | ◆ Avecia |
| ◆ Q-One Biotech Inc. | ◆ Irvine Scientific | ◆ TerraCell | |
| ◆ Charles River Laboratories | ◆ JRH Biosciences | ◆ Pall Life Sciences | |
| ◆ CUNO Incorporated | ◆ Newport Biosystems, Inc. | ◆ Serologicals Corporation | |