



Raw Materials & Disposable Systems for Mammalian Cell Products

July 18–20, 2005

Sunday, July 17

4:00–6:00 pm: **Registration, Welcome Reception, plus Exhibit and Poster Setup**

Monday, July 18

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: **Role of Supply Chain Audits in Supplier Qualification and Risk Minimization**
Thomas Parker — *Bristol-Myers Squibb*

9:15–10:00 am: **Emerging Viruses and Raw Materials**
Garry Takle, Ph.D. — *AppTec*

10:00–10:30 am: **Break** — Exhibit Area

10:30–11:15 am: **Building a Robust Raw Materials Program in Research and Development**
Steven Lane — *Eli Lilly and Company*

11:15–12:00 noon: **Plant-Produced Recombinant Proteins for Animal-Component-Free Cell Culture Media**
Ning Huang, Ph.D. — *Ventria Bioscience*

12:00–1:30 pm: **Lunch** — Exhibit Area

1:30–2:15 pm: **Problems Encountered During Method Transfer, Validation, or Testing of Vendor Test Methods**
Lina Patel, Ph.D. — *Diosynth Biotechnology*

2:15–3:00 pm: **Challenges of a Raw Material Chemistry Lab Among Cell Culture Science**
Daniel Lobato — *Micro-Virology Laboratories, Inc.*

3:00–3:30 pm: **Break** — Exhibit Area

3:30–4:15 pm: **Disposable Bioreactors: Biopharmaceutical Manufacturing in a Bag**
Leigh Pierce — *PacificGMP*

4:15–5:00 pm: **Panel Discussion**

6:00–7:30 pm: **Reception** — Exhibit Area

Tuesday, July 19

7:30–8:30 am: **American Breakfast** — Exhibit Area

8:30–9:15 am: **Rapid Improvement in Product Yield by Optimization of Peptone Combinations**
Matthew Jerums — *Amgen*

9:15–10:00 am: **Development of a Raw Materials/Utilities Program at a Biopharmaceutical Company**
Nataliya Afonina, Ph.D. — *ImClone Systems Incorporated*

10:00–10:30 am: **Break** — Exhibit Area

10:30–11:15 am: **Using Q-PCR for Mycoplasma Testing of Biopharmaceutical Products**
Audrey Chang, Ph.D. — *BioReliance, invitrogen bioservices*



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- 11:15–12:00 noon: **Starting from Scratch: Setting Up a Component and Vendor Qualification Program**
Annette Ragosta — *SAIC-Frederick, Inc.*
- 12:00–6:00 pm: **JRH Manufacturing Facility Tour**
- 6:00–9:00 pm: **Conference Banquet**

Wednesday, July 20

- 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**
- 10:30–12:00 noon: **Technical Workshops II**
- 12:00–1:30 pm: **Lunch — Exhibit Area**
- 1:30–2:15 pm: **Balancing the Needs of Clients, Contract Manufacturing, and Regulatory Compliance for Raw Materials**
Jay Treat, Ph.D. — *Avid Bioservices, Inc.*
- 2:15–3:00 pm: **Quality Agreements**
Rae Saltzstein — *Targeted Genetics Corporation.*
- 3:00–3:30 pm: **Break — Exhibit Area (Exhibit Tear Down at 3:30 pm)**
- 3:30–4:15 pm: **Strategies for Successful Technology Transfers**
Cynthia Wooge, Ph.D. — *SAFC Pharma*
- 4:15–5:00 pm: **Qualifying Raw Materials for GMP Manufacturing of Biopharmaceuticals**
Paula Shadle, Ph.D. — *Shadle Consulting*

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