



## **Raw Materials and Contract Services** **For Mammalian Cell Products**



### **SUNDAY, JULY 27, 2008**

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

### **MONDAY, JULY 28, 2008**

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

8:00-8:30 am **Introduction By Conference Co-Chairs**  
*Maureen Costello, PhD - Seraphim Life Sciences, LLC*  
*Edwin R. Fleischer - Amgen Inc.*

8:30-9:15 am **Vaccine Raw Materials - Procurement and Testing**  
*Abraham Thomas, PhD - Wyeth Biotech*

9:15-10:00 am **Auditing Contract Laboratories and Raw Material Suppliers**  
*Daniel Lobato - Quality Control & Quality Assurance Professional*

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

10:30-11:15 am **Raw Material Qualification and Supplier Management:  
Phase I through Commercial Manufacturing**  
*Gregory Page - Centocor*

11:15 am-noon **Critical Success Factors of Contract Analytical Testing in  
Support of Biopharmaceutical Products: Best Practices of  
Effective Partnerships**  
*Jon Kauffman, PhD - Lancaster Laboratories, Inc.*

Noon-1:30 pm **Lunch - Exhibit Area**

1:00-1:30 pm **Poster Session - Exhibit Area**

1:30-2:15 pm **Specification Development for Non-Compendial Materials**  
*Aurora Henry - Amgen Inc.*

2:15-3:00 pm **Considerations for the Definition and Supply Continuity of Critical  
Component Materials and Services**  
*Isaac Young - BioMarin Pharmaceutical, Inc.*

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

3:30-4:15 pm **What Heparin Recalls of 2008 Teach Us About Raw Material and  
API Control**  
*Paula Shadle, PhD - Shadle Consulting*

4:15-5:00 pm **Clinical Raw Material Supplier Quality**  
*Christine Covert - Amgen Inc.*

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

## TUESDAY, JULY 29, 2008

- 7:30-8:30 am **Breakfast - Exhibit Area**
- 8:30-9:15 am **Development and Use of a Raw Material Tracking Tool to Monitor Long-Term Perfusion Processes for Therapeutic Protein Production**  
*Jesse Keegan - Genzyme Corporation*
- 9:15-10:00 am **Contract Microbiology Services - Relevant Microbiological Issues**  
*Robert Guardino - AAIPharma, Inc.*
- 10:00-10:30 am **Break - Exhibit Area**
- 10:30-11:15 am **The Critical Role of Souring in Raw Material Qualification**  
*Lenwood Grant - Bristol-Myers Squibb*
- 11:15 am-Noon **Supplier Relationships, Qualification and Certification**  
*Lisa Milano - Genentech, Inc.*
- 1:00 pm **Board bus at hotel entrance - a "single-use" boxed-type lunch will be provided**
- 2:00-4:00 pm **Tour of Baxter Healthcare Contract Manufacturing Facility**  
*Note: All who sign up must complete and submit a confidentiality agreement prior to the tour. WilBio staff will be collecting them at the registration table.*
- 4:00-4:30 pm **Baxter reception following tour**
- 4:30 pm **Board the bus and return to hotel**

## WEDNESDAY, JULY 30, 2008

- 7:30-8:30 am **Breakfast - Exhibit Area**
- 8:30-9:15 am **Critical Quality Attributes for Raw Materials Used in Upstream and Downstream Processing and Process Understanding**  
*Duncan Low, PhD - Amgen Inc.*
- 9:15-10:00 am **A Proactive Approach to Supplier Management**  
*Lucy Cabral - Genentech, Inc.*
- 10:00-10:30 am **Break - Exhibit Area**
- 10:30-11:15 am **Strategies for Assessing the Impact of Temperature Excursions on Raw Materials**  
*Susan Lenk, PhD - Centocor, Inc.*
- 11:15 am-Noon **Regulatory Considerations for Contract Manufacturing**  
*Chiang Syin, PhD - FDA/CBER*
- Noon-1:30 pm **Lunch - Exhibit Area**
- 1:00-1:30 pm **Poster Session - Exhibit Area**
- 1:30-2:15 pm **Implementation Strategies for Raw Material Control in Mammalian Cell-Based Bioprocesses**  
*Gregory Beck, PhD - Eli Lilly & Company*
- 2:15-3:00 pm **Mitigating Material Risks for Supply Chain Continuity**  
*Tom Dinka - Doe & Ingalls of NC*
- 3:00-3:30 pm **Break - Exhibit Area**
- 3:30-4:15 pm **Outsourced Production Services: Quality and Regulatory Considerations**  
*Maureen Costello, PhD - Seraphim Life Sciences, LLC*
- 4:15-5:00 pm **Collection Management of Cellular Raw Materials in Clinical-Stage Trials of Autologous Cellular Therapeutics**  
*Edward Scott, MD - Lifeblood Biological Services*

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