



The Most Trusted Source of BioProcess Technology®

San Juan, Puerto Rico



Complimentary Pre-Conference Workshop on:
Raising Money for Antibody Development
Funding Each Stage of the Scale-Up Process

Chaired by Patrick Huddie, Ph.D. -
Evergreen Capital LLC
Sunday, April 22 from 4:00-6:30 PM



The Waterside Conference

April 23-25, 2007

Scale-Up and Production of Recombinant & Monoclonal Antibodies

A substantial body of knowledge has been developed on large-scale manufacturing practices for these proteins, but it remains difficult to establish or maintain a fully integrated process than can be reproduced and validated. At the same time, many applications are moving toward the use of human molecules, which present additional development and scale-up challenges.

Please join us as we explore the problems faced while taking antibody-based products through development and into large-scale production. This meeting will showcase the industry's more successful efforts as we focus on recent advances in cell culture, analytical, and purification methods; plus trends in facility design and regulatory practices. Posters, workshops, and approximately 60 exhibits will then be used to supplement the program with details on the vital technologies and services needed for success.

Sponsored By:



GE Healthcare



DMV International
The ingredients of success



IrvineScientific

Topics Include:

- Cell Line Development
- Expression Optimization
- Product Characterization
- Stability and Storage
- Purification
- Assay Development
- Safety Testing
- Conjugation and Formulation
- Regulatory Issues
- Post-Approval Issues
- Single-Use Components





The Waterside Conference

Scale-Up and Production of Recombinant and Monoclonal Antibodies

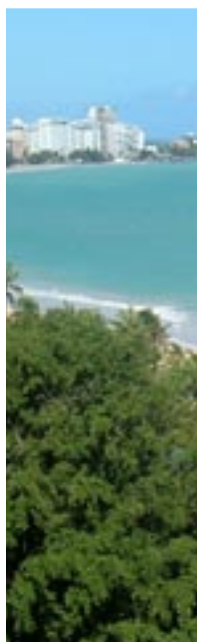
SUNDAY, APRIL 22, 2007

- 3:00-6:00 pm **Registration and Welcome Reception**
- 4:00-6:00 pm **Raising Money Workshop - Main Meeting Room**

MONDAY, APRIL 23, 2007

- 7:00-8:00 am **Registration, Continental Breakfast — Meeting Room Foyer**
- 8:00-8:30 am **Introduction**
Keith L. Carson – Conference Chairman
- 8:30-9:15 am **Protein A Affinity Chromatography: Novel Media and New Insights into Mass Transfer Mechanism**
Alois Jungbauer, Ph.D. – Austrian Center of Biopharmaceutical Technology
- 9:15-10:00 am **Investigating Protein-Protein Interactions for Monoclonal Antibodies Using Self-Interaction Chromatography**
Joy Adiletta – Amgen
- 10:00-10:30 am **Break — Exhibit Area**
- 10:30-11:15 am **Capillary Electrophoresis: A Practical Characterization Tool of Therapeutic Monoclonal Antibodies**
Oscar Salas-Solano, Ph.D. – Genentech, Inc.
- 11:15-Noon **Trying to Consistently Find the Sweet Spot for Antibody Expression**
Robert DuBridges, Ph.D. – PDL BioPharma, Inc.
- Noon-1:30 pm **Lunch and Poster Session — Exhibit Area**
- 1:30-2:15 pm **Cation Exchange Chromatography (CEX) Process Development**
Jonida Basha – Merck and Co., Inc.
- 2:15-3:00 pm **Development of a Robust Chemically-Defined and High-Yielding GS-CHO Platform Production Process**
NingNing Ma, Ph.D. – Pfizer, Inc.
- 3:00-3:30 pm **Break — Exhibit Area**
- 3:30-4:15 pm **Product Characterization of Recombinant Proteins and Monoclonals**
Kathy Hanley, Ph.D. – CBR International Corp.
(co-authored by Jeanne Novak, Ph.D. - CBR International Corp.)
- 4:15-5:00 pm **Changes in Cell Culture Process Development Accelerate Entry into GMP Production**
Gerald Carson – Abbott Laboratories
- 5:00-5:45 pm **Investigation of an Apparent Potency Change During Development of a Commercial Monoclonal Antibody Production Process**
Stephen Notarnicola, Ph.D. – Biogen Idec
- 6:00-7:30 pm **Reception — Exhibit Area**

Continued on page 2



TUESDAY, APRIL 24, 2007

- 7:30-8:30 am **American Breakfast — Exhibit Area**
- 8:30-9:15 am **Towards Commercialization: Cell Culture Platform Development for Monoclonal Antibody**
Tongtong Wang, Ph.D. – Eli Lilly & Company
- 9:15-10:00 am **Finding the Hidden Specificities in Monoclonal Antibodies: Antibodies to Drug Metabolites**
Richard Root, M.Sc. – Roche Diagnostics Corp.
- 10:00-10:30 am **Break — Exhibit Area**
- 10:30-11:15 am **Ceramic Hydroxyapatite Chromatography in Antibody and Fc-fusion Protein Purification**
Shujun Sun, Ph.D. – Wyeth Biotech
- 11:15-Noon **Evicting Hitchhiker Antigens that Stow Away on Your Antibodies: A Case Study on the Elimination of Antigen Contaminants During Antibody Purification**
Missag Parseghian, Ph.D. – Peregrine Pharmaceuticals
- Noon-6:00 pm **Free Afternoon with Recommended Activities**
- 6:30-9:30 pm **Conference Banquet**

WEDNESDAY, APRIL 25, 2007

- 7:30-8:30 am **Breakfast — Exhibit Area**
- 8:30-10:00 am **Technical Workshops I**
- 10:00-10:30 am **Break — Exhibit Area**
- 10:30-Noon **Technical Workshops II**
- Noon-1:30 pm **Lunch and Poster Session - Exhibit Area**
- 1:30-2:15 pm **Cell Culture Process Development and Technology Transfer: A Tale of Three Antibody Projects**
Shue-Yuan Wang, Ph.D. - Abbott Bioresearch Center
- 2:15-3:00 pm **A Simple Method for Enhancing Capacity and Aggregate Removal in Ion Exchange and Mixed Mode Chromatography**
Peter Gagnon – Validated Biosystems, Inc.
- 3:00-3:30 pm **Break — Exhibit Area (Exhibit and Poster Teardown at 3:30 pm)**
- 3:30-4:15 pm **High-Titre, Stable Cell Lines Using an Optimized Process and Novel Synthetic Genetic Elements**
Cori Gorman, Ph.D. – Selexis SA