

# The Waterside Conference

*Process Development and Production Issues*

*For Monoclonal & Recombinant Antibodies*

**8th Annual Meeting**

May 04-07, 2003

San Francisco, California

## Topics Include:

- Cell Line Selection
- Expression Enhancement
- Product Characterization
- Stability & Storage
- Purification
- Assay Development
- Safety Testing
- Conjugation and Formulation
- Regulatory Issues
- Post Approval Issues
- Raw Material Screening

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 that 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 50 exhibits will then be used to supplement the program with details on the vital technologies and services needed for success.

## Hotel Accommodations

The Hyatt Regency Hotel has offered a special rate of \$189 per night plus applicable sales tax. All reservations must be made directly with the hotel:

**Hyatt Regency Hotel**  
**5 Embarcadero Center**  
**San Francisco, CA 94111**  
**(415) 788-1234**

To receive the conference rate of \$189, you must reserve your room no later than April 14, 2003, and specify you will be attending The Waterside Conference.

## Sponsored by:



## ***Monoclonal & Recombinant Antibodies***

May 4-7, 2003

### **Sunday, May 4:**

- 10:00 - 1:00 pm: **Registration and Exhibit Setup**
- 1:00 - 1:30 pm: **Introduction**  
Keith L. Carson – Conference Chairman
- 1:30 - 2:15 pm: **Strategy, Execution, and Results of a 2nd-Generation CHO-Based Cell Culture Process Transfer**  
Eric Fallon - *IDEC Pharmaceuticals*
- 2:15 - 3:00 pm: **Human Monoclonal Antibodies Expressed in CHO Cell Lines: Selection of High Producer Clones and Production in Protein Free Medium**  
Yoav Roth - *XTL Biopharmaceuticals Ltd.*
- 3:00 - 3:30 pm: **Break - Exhibit Area**
- 3:30 - 4:15 pm: **Cell Line Engineering for Production of Therapeutic Antibody Glycoforms with Increased Biological Activity**  
Pablo Umana, Ph.D. - *GLYCART biotechnology*
- 4:15 - 5:00 pm: **Optimization of Antibody Production from CHO Cell Lines by Re-Transfection to Balance Expression of Heavy and Light Chain Polypeptides**  
Daniel Allison, Ph.D. - *ICOS Corporation*
- 5:00 - 5:45 pm: **Speed, Yield, Quality - Bringing An Upstream Process Platform to New Performance Levels**  
Thomas Seewoester, Ph.D. - *Amgen, Inc.*
- 6:00 - 7:30 pm: **Welcome Reception- Exhibit Area**

### **Monday, May 5:**

- 7:30 - 8:30 am: **Continental Breakfast - Exhibit Area**
- 8:30 - 9:15 am: **Enhanced Antibody Production Yields from NS0 Cells**  
Amit Varma, Ph.D. - *MedImmune, Inc.*
- 9:15 - 10:00 am: **Clinical Manufacturing of Fc-Fusion Proteins in Chinese Hamster Ovary Cell Suspension Cultures**  
Scott Carver, Ph.D. - *Regeneron Pharmaceuticals, Inc.*
- 10:00 - 10:30 am: **Break - Exhibit Area**
- 10:30 - 11:15 am: **Selection, Design, and Production of Therapeutic Antibody Fragments**  
Andrew Chapman - *Celltech Chiroscience Ltd.*
- 11:15 - 12:00 noon: **Improving Sample Preparation and Analytical Tools to Support Monoclonal Antibody Manufacturing**  
Jacob Bongers - *GlaxoSmithKline*
- 12:00 - 1:30 pm: **South of Market Lunch Buffet - Exhibit Area**
- 1:30 - 2:15 pm: **The Evolution of a Monoclonal Antibody Downstream Process from GLP through Phase III**  
Elsie DiBella - *Centocor, Inc.*
- 2:15 - 3:00 pm: **A Case Study in Collaborative Manufacturing**  
Jeffrey Robbins, Ph.D. - *Inhibitex, Inc.*
- 3:00 - 3:30 pm: **Break - Exhibit Area**

- 3:30 - 4:15 pm: **Mass Spectrometric Analysis of Heterogeneity in Monoclonal Antibodies**  
Victor Ling- *Genentech, Inc.*
- 4:15 - 5:00 pm: **Development of Novel Flexible Cell Culture Devices for Small-Scale Antibody Production from Anchorage-Dependent and Suspension Cell Lines**  
Richard Root - *Roche Diagnostics*
- 5:00 - 5:45 pm: **Development of a High Yielding Humanized Antibody Manufacturing Process on a Myeloma Platform, and Assessment of Product Comparability**  
Mark Backer, Ph.D. - *Protein Design Labs*
- 6:00 – 7:30 pm: ***The Golden Gate Reception- Exhibit Area***

**Tuesday, May 6:**

- 7:30 - 8:30 am: ***American Breakfast - Exhibit Area***
- 8:30 - 9:15 am: **Perfusion Culture for the Production of a Monoclonal Antibody**  
Jean-Francois Hamel – *Massachusetts Institute of Technology*
- 9:15 - 10:00 am: **Controlling Glycosylation of Antibodies in Plants**  
Kerr Anderson, Ph.D. - *Dow Plant Biopharmaceutical*
- 10:00 - 10:30 am: ***Break - Exhibit Area***
- 10:30 - 11:15 am: **Using Statistical Design in the Development of a Histidine-Based Lyophilized Formulation Containing a High Monoclonal Antibody Concentration**  
Bei Chen, Ph.D. - *Abgenix, Inc.*
- 11:15 - 12:00 noon: **Effect of Cell Culture Process Changes on the Stability of a Humanized Monoclonal Antibody**  
Supriya Gupta, Ph.D. - *Protein Design Labs*
- 7:00 - 10:00 pm: ***Gala Banquet – Atrium***

**Wednesday, May 7:**

- 7:30 - 8:30 am: ***Continental Breakfast - Exhibit Area***
- 8:30 - 10:00 am: **Technology Workshops I**
- 10:00 - 10:30 am: ***Break - Exhibit Area***
- 10:30 - 12:00 noon: **Technology Workshops II**
- 12:00 - 1:30 pm: ***It's a Wrap Buffet - Exhibit Area***
- 1:30 - 2:15 pm: **Integrated Strategies for Monoclonal Antibody Process Development and Scale-Up**  
Brendan Fish, Ph.D. - *Cambridge Antibody Technology*
- 2:15 - 3:00 pm: **Physio-Chemical Analysis & Characterization of IgG4 rMAbs & Half-Molecules**  
Brooks Sunday, Ph.D. - *Schering-Plough Research Institute*
- 3:00 - 3:30 pm: ***Break - Exhibit Area (Exhibit Tear Down at 3:30 pm)***
- 3:30 - 4:15 pm: **Evaluation of Viral Clearance Using Viresolve NFR Technology**  
Kimberly Bratberg - *IDEC Pharmaceuticals*
- 4:15 - 5:00 pm: **Use of Statistically Designed Experiments to Characterize the Robustness of Column Unit Operations**  
Michelle Butler - *Genentech, Inc.*
- 5:00 - 5:45 pm: **Hydrophobic Charge Induction Chromatography: A Novel Technique for Isolation and Purification of Antibodies**  
Warren Schwartz, Ph.D. – *Ciphergen Biosystems, Inc.*

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