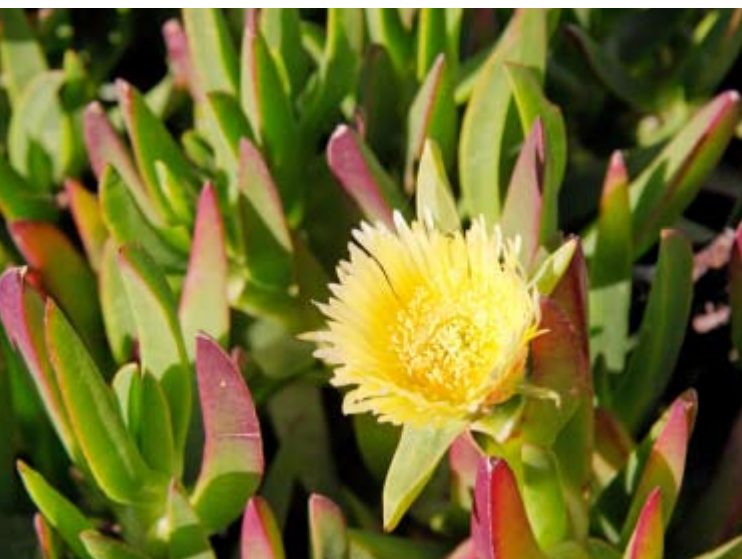


14th International Meeting • South San Francisco, California



The Waterside Conference

April 20-22, 2009

Scale-Up and Production of Recombinant and 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 that can be reproduced and validated. At the same time, many applications are moving toward the use of human mofdules, 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, technical workshops, and exhibits will then be used to supplement the program with details on the vital technologies and services needed for success.

Conference Chair:

Yung-Hsiang Kao, PhD – Genentech, Inc.

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TOPICS:

- 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





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SUNDAY, APRIL 19, 2009

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

MONDAY, APRIL 20, 2009

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

8:00-8:30 am **Introduction by Conference Chair**
Yung-Hsiang Kao, PhD - *Genentech, Inc.*

8:30-9:15 am **Freeze/Thaw Processing and the Stability of Monoclonal Antibodies**
Vineet Kumar, PhD - *Abbott Bioresearch Center*

9:15-10:00 am **Inhibiting Co-Elution of Host Cell Proteins and Antibody During Protein A Affinity Chromatography**
Kathlyn Lazzareschi - *Genentech, Inc.*

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

10:30-11:00 am **Technical Workshop - BIOLOG**

11:00-11:30 am **Technical Workshop - CUNO Incorporated, a 3M company**

11:30 am-Noon **Technical Workshop - EMD Chemicals, Inc.**

Noon-1:30 pm **Lunch and Poster Session - Exhibit Area**

1:30-2:15 pm **Recent Improvements in Fungal Platform for Production of Recombinant Antibodies**
W. Dorsey Stuart, PhD - *Neugenesis Corporation*

2:15-3:00 pm **Fv-Based Dual Affinity Re-Targeting (DART) Proteins: Challenges and Solutions During Development**
Syd Johnson, PhD - *MacroGenics, Inc.*

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

3:30-4:15 pm **Antibody Reduction and More Recent Challenges to the Scale-Up of CHO Manufacturing Processes**
Corinna Sonderegger, PhD - *Sandoz GmbH*

4:15-5:00 pm **Case Study: Using Depth Filtration for Primary Clarification of Mammalian Cell Culture**
Brandon Christensen - *Medimmune, Inc.*

5:00-5:45 pm **Development of an Improved Feed for GS-CHO Fed-Batch Processes**
Jennifer Purdie - *Eli Lilly & Company*

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



The Waterside Conference

TUESDAY, APRIL 21, 2009

- 7:30-8:30 am **Breakfast - Exhibit Area**
- 8:30-9:15 am **Characterization of Abatacept – A Novel Therapeutic Agent for the Treatment of Rheumatoid Arthritis**
Satish Mallya, PhD - *Bristol-Myers Squibb*
- 9:15-10:00 am **High Throughput NMR for Monitoring Complex Media in Mammalian Cell Culture**
Ying Luo, PhD - *Amgen, Inc.*
- 10:00-10:30 am **Break - Exhibit Area**
- 10:30-11:15 am **Antibody Disulfide Bond Reduction in CHO Production Processes**
Michael Laird, PhD - *Genentech, Inc.*
- 11:15 am-Noon **Design Practical Approaches to Improve Strong Antibody Molecule Self-Interaction During Purification Process**
Greg Conley - *Dyax Corporation*
- Noon-12:45 pm **Frequently Misunderstood and/or Misapplied Guidances: ICH Q8, Q9, and Q10. A Regulatory Perspective**
Barbara Rellahan, PhD - *FDA CDER*
- Free Afternoon with Recommended Group Activities**

WEDNESDAY, APRIL 22, 2009

- 7:30-8:30 am **Breakfast - Exhibit Area**
- 8:30-9:15 am **Rapid Process Development, Scale-Up, and Tech Transfer Strategies Using a Platform Technology**
Girish Pendse, PhD - *ImClone Systems, a wholly-owned subsidiary of Eli Lilly & Co.*
- 9:15-10:00 am **Understanding the Mechanism of Antibody Reduction in a CHO Manufacturing Process**
Yung-Hsiang Kao, PhD - *Genentech, Inc.*
- 10:00-10:30 am **Break - Exhibit Area**
- 10:30-11:00 am **Technical Workshop - Pall Life Sciences**
- 11:00-11:30 am **Technical Workshop - Bio-Rad Laboratories**
- 11:30 am-Noon **Technical Workshop - Cobra Biomanufacturing Plc**
- Noon-1:30 pm **Lunch and Poster Session - Exhibit Area**
- 1:30-2:15 pm **Advances in Platform Fed-Batch and XD Production Processes Using the PER.C6 Human Cell Line**
John Chon, PhD - *PERCIVIA, LLC*
- 2:15-3:00 pm **HTRF in Antibody Development**
Esohe Idusogie, PhD - *Oncomed Pharmaceuticals, Inc.*
- 3:00-3:30 pm **Break - Exhibit Area**
- 3:30-4:15 pm **Scale-Down Systems for Clonal Cell Line Selection and Process Characterisation**
Gareth Lewis, PhD - *MedImmune Limited*
- 4:15-5:00 pm **Antibody Disulfide Bond Reduction Mitigation Strategies**
Peter K. Lambooy, PhD - *Eli Lilly & Company*
- 5:00-5:45 pm **Case Study: Implementation of High Density Cell Banking Technology in Manufacturing of Therapeutic Proteins from CHO Cell Lines**
Yiwen Tao - *Biogen Idec Inc.*

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