

The Waterside Conference

Process Development and Production Issues for Monoclonal & Recombinant Antibodies

2nd Annual Meeting

April 14-17, 1997

Waterside Marriott Hotel

Norfolk, Virginia

Program

Sunday, April 13

4:00-10:00 pm: **Welcome Reception, Exhibit Set-Up**

Monday, April 14

7:00-8:00 am: **Check In - Coffee**

8:00-8:30 am: **Introduction**
Keith L. Carson - Conference Chairman

8:30-9:15 am: **A Comprehensive Strategy for the Characterization of a Monoclonal Antibody**
Michael G. Mulkerrin, Ph.D. - *Genentech, Inc.*

9:15-10:00 am: **Assay Specificity: Determination of Antibody Titer in Conditioned Media**
Amy Dingley, Ph.D. - *Biogen*

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

10:30-11:15 am: **Investigating Alternatives to Transferrin**
Paul Sauer - *Protein Design Labs*

11:15-12:00 noon: **Optimization of Monoclonal Antibody Production in a Protein-Free System Using Continuous Flow Centrifugation**
Christopher W. Kemp, Ph.D. - *Kemp Biotechnologies*

12:00-1:30 pm: **Lunch - Exhibit Area**

1:30-2:15 pm: **Viral Safety Issues for Monoclonal Antibody Production**
Judith Sernatinger - *Biogen*

2:15-3:00 pm: **Factors Involved in the Development and Validation of Assays for Characterizing Monoclonal Antibodies**
Ram Seetharam, Ph.D. - *Microbiological Associates*

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

3:30-4:15 pm: **The Finer and Less Understood Points to Consider for Monoclonal Antibodies**
Christopher C. Joneckis, Ph.D. - *FDA/CBER*

4:15-5:00 pm: **Dealing With Process Changes in a Manufacturing Setting**
Maureen A. Costello, Ph.D. - *SmithKline Beecham*

5:00-5:45 pm: **Licensing the First Therapeutic Monoclonal Antibody**
Eileen M. Hanigan - *R.W. Johnson PRI*

6:00-8:00 pm: **The Waterside Reception - Exhibit Area**

Tuesday, April 15

7:30-7:45 am: **Continental Breakfast - Exhibit Area**

- 7:45-8:30 am: **Development and Characterization of a Recombinant Anti-Tumor Fab-Superantigen Fusion Protein - A Case Study**
Ebba Florin-Robertsson, Ph.D. - *Pharmacia & Upjohn*
- 8:30-9:15 am: **Process Improvements for the Production of a Humanized Monoclonal Antibody**
Phillip C. Familletti - *Hoffmann-LaRoche*
- 9:15-10:00 am: **Application of On-Line Monitoring for Optimizing the Production of Monoclonal Antibodies**
Sedettin S. Ozturk, Ph.D. - *Bayer Corporation*
- 10:00-10:30 am: **Break - Exhibit Area**
- 10:30-11:15 am: **From R&D to Manufacturing: The Evolution of a MAb Production Process**
Eric Tsao, Ph.D. - *MedImmune, Inc.*
- 11:15-12:00 noon: **Effects of Aggregates on the Preparation of Purified Monoclonal Antibodies**
David Buck - *Amcell Corporation*
- 12:00-12:45 pm: **Intensification of a Large Scale Commercial Monoclonal Antibody Purification Process**
Richard H. Francis - *Centocor B.V.*
- 6:30-8:00 pm: **Banquet - The Spirit of Norfolk**

Wednesday, April 16

- 7:30-8:30 am: **Continental Breakfast - Exhibit Area**
- 8:30-10:00 am: Technology Workshops
- 10:00-10:30 am: **Break - Exhibit Area**
- 10:30-11:15 am: **Analytical Tools for Formulation Development**
Brent R. Larsen, Ph.D. - *Protein Design Labs*
- 11:15-12:00 noon: **Implementing Total Organic Carbon Analysis for Cleaning Validation**
Carl Craig, Ph.D. - *Sievers Instruments*
- 12:00-1:30 pm: **Lunch - Exhibit Area**
- 1:30-2:15 pm: **Lessons Learned in Monoclonal Antibody Development and Manufacturing**
Gordon Pugh - *Lonza Biologics plc*
- 2:15-3:00 pm: **Development and Validation of a Monoclonal Antibody Production Process Using Statistical Experimental Design**
Christian Knaack - *Biomira, Inc.*
- 3:00-3:30 pm: **Break - Exhibit Area (Exhibit Tear Down at 3:30 pm)**
- 3:30-4:15 pm: **Antibody Purification Using High Performance Tangential Flow Filtration**
Steven S. Mundt - *Cytogen Corporation*
- 4:15-5:00 pm: **Formulating Solutions for Product Development: Some Points to Consider**
Ben Isaacs - *Formatech, Inc.*
- 5:00-5:45 pm: **Monoclonal Antibody Purification - Development of a "Robust" Process**
Gregory S. Blank, Ph.D. - *Genentech, Inc.*
- 7:00-10:00 pm: **Nauticus Reception**

Thursday, April 15

- 7:30-8:30 am: **Continental Breakfast - Foyer**
- 8:30-9:15 am: **Strategies for Removal of Antibody-Complexed DNA and Endotoxin**
Peter Gagnon, Ph.D. - *Validated Biosystems*
- 9:15-10:00 am: **Issues in Optimizing Purification Processes for Monoclonal Based Products**
Michael Lennick, Ph.D. - *Medarex*
- 10:00-10:30 am: **Break - Foyer**
- 10:30-11:15 am: **Large-Scale Protein-A Affinity Chromatography of Immunoadhesins**

Steven M. Chamow, Ph.D. - *Genentech, Inc.*

Strategies for Successful Antibody Conjugation

Gregory Hermanson - *Pierce Chemical Company*

11:15-12:00 noon: