

The Waterside Conference

Process Development and Production Issues for Monoclonal & Recombinant Antibodies

3rd Annual Meeting

April 27-30, 1998

Norfolk, Virginia

Program

Sunday, April 26

4:00-9:00 pm: **Welcome Reception, Exhibit Set-Up**

Monday, April 27

7:00-8:00 am: **Continental Breakfast - Meeting Room Foyer**

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

8:30-9:15 am: **Host Cell Protein Assays**
Stephen Flatman, Ph.D., BSc - *LONZA Biologics, PLC*

9:15-10:00 am: **Characterization of a Therapeutic Anti-Human TNF α Chimeric Monoclonal IgG**
Donald S. Neblock, Ph.D. - *Centocor*

10:30-11:15 am: **Monoclonal Antibodies - Analytical Methods and Techniques for the Identification and Characterization of Post-Translational Modifications of Monoclonal Antibodies**
Patrick Gearing, Ph.D. - *Coulter Pharmaceutical, Inc.*

11:15-12:00 noon: **Antibody Mediated Complement Dependent Cell Killing is Correlated to the Structure of the N-Linked Oligosaccharide of the FcDomain**
Michael G. Mullkerrin, Ph.D. - *Genentech, Inc.*

1:30-2:15 pm: **Production and Characterization of Human anti-TNF**
Brian G. Turner, Ph.D. - *BASF Bioreserach Corporation*

2:15-3:00 pm: **Viral Clearance Validation of a Biopharmaceutical Manufacturing Process: A Case Study of a Monoclonal Antibody**
Robert T. Bartlett - *Hoffmann - LaRoche*

3:30-4:15 pm: **Increasing the Yield of Monoclonal Antibody Production in Hollow Fiber Bioreactors with Extended Extracapillary Space**
Yuan Shi, Ph.D. - *Unisyn Technologies, Inc.*

4:15-5:00 pm: **Large Scale Manufacture of Monoclonal Antibodies**
Ben A. Bulthuis, Ph.D. - *Centocor*

Tuesday, April 28

8:15-9:15 am: **Comparability Characterizations for a Monoclonal Antibody: Case Study Supporting PROSTASCINT Development**
David Farb, Ph.D. - *CYTOGEN Corporation*

9:15-10:00 am: **Factors Involved in the Formatulation Development of Monoclonal Antibodies**

John E. McEntire, Ph.D. - *MA BioServices, Inc.*

Lessons Learned and Prices Paid in Monoclonal Antibody Purification

Gerr L. Bell, MS - *Boehringer Ingelheim*

Virus Validation Method Development for Monoclonal Antibody Purification

Yuan Xu, Ph.D. - *Genentech, Inc.*

10:30-11:15 am:

11:15-12:00 noon:

Wednesday, April 29

8:30-10:00 am:

Technology Workshops

10:30 - 12:00 noon:

Panel Discussion - Technology Transfer and Comparability

Maureen A. Costello, Ph.D. (Panel Chair) - *SmithKline Beecham*

1:30-2:15 pm:

Analytical Technical Transfer

John J. Dougherty, Ph.D. - *Lilly Research Laboratories*

2:15-3:00 pm:

Regulatory Perspectives

Christopher C. Joneckis, Ph.D. - *CBER/FDA*

3:30-4:15 pm:

Meeting the Challenge for Process Development of Cost Effective, Approvable and Robust Processes

Richard Francis - *Glaxo Wellcome Development Laboratories*

4:15-5:00 pm:

Development & Automation of a Perfusion Bioreactor for Monoclonal Antibody Production

Tracy L. Hoffman - *Abbott Laboratories*

Thursday, April 30

8:30-9:15 am:

A Case Study on IgM Purification

Robert F. Brunhouse, Ph.D. - *PanAb*

9:15-10:00 am:

Monoclonal Antibodies: Evolution to Mainstream Therapeutics

Roland Newman, Ph.D. - *IDEC Pharmaceutical Corporation*

10:30-11:15 am:

Use of Thiophilic Resins in the Purification of Monoclonal IgG

Alex Schwarz, Ph.D. - *Nextran, Inc.*

11:15-12:00 noon:

Developing Monoclonal Antibodies as Growth Factor Receptor Antagonists

John A. Gilly, Ph.D. - *ImClone Systems, Inc.*