

# The Waterside Conference

Process Development and Production Issues for Monoclonal & Recombinant Antibodies

## 4th Annual Meeting

April 12-15, 1999

Sheraton Waterside Hotel

Norfolk, Virginia

## Program

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### Sunday, April 11

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

### Monday, April 12

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: **Characterization of Human Monoclonal Antibodies**  
Helen Chadd, Ph.D. - *Abgenix, Inc.*

9:15-10:00 am: **Development of a Generic, High-Yielding Fed Batch Process**  
Paul Sauer, Ph.D. - *Protein Design Labs*

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

10:30-11:15 am: **Characterization of Components in Animal Protein Free Cell Culture Media**  
Jonathan Klepinger - *ICOS Corporation*

11:15-12:00 noon: **cGMP Production of Monoclonal Antibodies Using Disposable Components**  
Girish Pendse, Ph.D. - *Baxter Hyland Immuno*

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

1:30-2:15 pm: **Validation Studies to Support Licensure of the Lenercept Recovery Process**  
Marjorie Winkler, Ph.D. - *Genentech, Inc.*

2:15-3:00 pm: **The Issues Encountered in Developing the Fermentation Stage of a Monoclonal Antibody Production Process**  
Richard Francis - *Glaxo Wellcome*

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

3:30-4:15 pm: **Product Comparability**  
Christopher C. Joneckis, Ph.D. - *FDA/CBER (Invited)*

4:15-5:00 pm: **Formulation Development Studies with a Recombinant Therapeutic Monoclonal Antibody Agent**  
Paul DelMonte, Ph.D. - *SmithKline Beecham*

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

### Tuesday, April 13

7:30-8:30 am: **Continental Breakfast - Exhibit Area**

8:30-9:15 am: **Recovery of Recombinant Antibodies from Unclarified Chinese Hamster Ovary Cell Culture Fluid by Expanded Bed Protein A Affinity Chromatography**

Gerardo Zapata, Ph.D. - *Genentech, Inc.*

**The Fed Batch - A Simple But Efficient Approach to Accelerate Drug Development Projects**

Thomas Seewoester, Ph.D. - *BASF Bioreserach Corp.*

9:15-10:00 am:

10:00-10:30 am:

**Break - Exhibit Area**

**Achievement of a High Cell Density and High Antibody Productivity by a Fed-Perfusion Bioreactor Process**

Jeng-Dar Yang, Ph.D. - *Immunomedics, Inc.*

10:30-11:15 am:

**Purification of Monoclonal Antibodies: There's More Than One Way to Skin a Cat**

Gerry Bell, Ph.D. - *Boehringer Ingleheim*

11:15-12:00 noon:

**Mixer - Happy Hour**

6:00-7:30 pm:

**Wednesday, April 14**

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:

**Lunch - Exhibit Area**

1:30-2:15 pm:

**Process Development and Scale-Up for Mammalian Cell Culture**

Mike Brown, Ph.D. - *Lonza Biologicals plc*

2:15-3:00 pm:

**A Retrospective Evaluation of the Hollow Fiber Bulk Production of 3-48S2 Murine Monoclonal Antibodies**

Robert J.W. Pentney, Ph.D. - *Bio Validations*

3:00-3:30 pm:

**Break - Exhibit Area (Exhibit Tear Down at 3:30 pm)**

3:30-4:15 pm:

**Influence of Monoclonal Antibody Manufacturing Processes On Product Stability**

Catherine Bentley, Ph.D. - *Glaxo Wellcome*

4:15-5:00 pm:

**Nutrient Feeding Strategy Development for High Performance Fed-Batch Cultivation of Mammalian Cells**

Weichang Zhou, Ph.D. - *Merck & Co.*

7:00-10:00 pm:

**Conference Banquet - Spirit of Norfolk Cruise**

**Thursday, April 15**

7:30-8:30 am:

**Continental Breakfast - Foyer**

8:30-9:15 am:

**Characterization of Fully Human Recombinant Antibodies**

Kathleen L. Grant, Ph.D. - *BASF Bioreserach Corp.*

9:15-10:00 am:

**Purification of Murine IgG1 Clinical Supplies at a Government Owned, Contractor Operated (GOCO) Pilot Plant**

Dennis Michiel, Ph.D. - *NCI/SAIC*

10:00-10:30 am:

**Break - Foyer**

10:30-11:15 am:

**Development of the Synagis? Commercial Manufacturing Process**

Eric Tsao, Ph.D. - *MedImmune*

11:15-12:00 noon:

**Serum Free Media Development for Monoclonal Antibody Production in High Cell Density Perfusion Bioreactors**

Mina Mahadevan, Ph.D. - *Medarex*