

The Waterside Conference

Process Development and Production Issues for Monoclonal & Recombinant Antibodies

6th Annual Meeting

May 7-10, 2001

The Wyndham Miami Beach Resort

Miami, Florida

Program

Sunday, May 6

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

Monday, May 7

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: **Development and Use of Homologous CHEF1 Promoter Vectors for Rapid Isolation of CHO Cell Lines Expressing High Levels of Recombinant Antibody**

Daniel Allison - ICOS Corporation

9:15 - 10:00 am: **Medium Studies During Production of Monoclonal Antibodies in Traditional and Novel Bioreactors**

Jean-Francois P. Hamel - *Massachusetts Institute of Technology*

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

10:30 - 11:15 am: **Use of a Microbial Expression System for Production of Antibody Domains**

Marc Better, Ph.D. - *Xoma Corporation*

11:15 - 12:00 noon: **Challenges in the Development, Scale-Up and Validation of a Large-Scale Recovery Process Step**

David Kahn - *Genentech, Inc.*

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

1:30 - 2:15 pm: **Large Scale Recovery of Antibody from Cell Culture using TFF**

Vijay Chiruvolu, Ph.D. - *Hoffmann-La Roche*

2:15 - 3:00 pm: **PCR Based Methods for Retrovirus Safety Evaluation of MAb Manufacturing Processes**

Kurt Brorson, Ph.D. - *FDA, CBER*

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

3:30 - 4:15 pm: **Manufacture and Use of MAbs as Therapeutic Agents**

Yashwant M. Deo, Ph.D. - *Medarex, Inc.*

4:15 - 5:00 pm: **Production of Antibody in a new Facility - Problems and Resolutions**

David M. Abercrombie, Ph.D. - *Centocor, Inc*

6:00 - 8:00 pm: *Miami Beach Reception - Exhibit Area*

Tuesday, May 8

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

- 8:30 - 9:15 am: **Practical Approaches for Bioreactor Yield Enhancement**
Eric Tsao, Ph.D. - *MedImmune, Inc.*
- 9:15 - 10:00 am: **Development of Multidose Product for Monoclonal Antibody Using Experimental Design Techniques: A Case Study**
Elizabet Kaisheva, Ph.D. - *Protein Design Labs, Inc.*
- 10:00 - 10:30 am: **Break - Exhibit Area**
- 10:30 - 11:15 am: **Analytical Methods and Techniques for the Identification and Characterization of Post-Translational and Modifications of Monoclonal Antibodies**
Patrick Gearing, Ph.D. - *Coulter Pharmaceutical, Inc.*
- 11:15 - 12:00 noon: **Free Thiol Issues in the Production of a Recombinant Antibody**
Reed J. Harris - *Genentech, Inc.*
- 6:00 - 7:30 pm: **Mixer • Happy Hour** - Exhibit Area

Wednesday, May 9

- 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: **Strategies for Manufacturing Monoclonal Antibody Products**
Richard Francis - *Glaxo Wellcome*
- 2:15 - 3:00 pm: **The Rationale for and Development of Super High Affinity Monoclonal Antibodies for InVivo Imaging and Therapy**
Simon J Y Saxby - *KS BioMedix Ltd*
- 3:00 - 3:30 pm: **Break - Exhibit Area (Exhibit Tear Down at 3:30 pm)**
- 3:30 - 4:15 pm: **Rapid Specificity Screening of Monoclonal Antibodies for the Development of Reagents for Drug Diagnostic Use**
Richard T. Root - *Roche Diagnostics*
- 4:15 - 5:00 pm: **Rapid Development of Monoclonal Antibodies Using RIMMS**
Katherine E. Kilpatrick - *Glaxo-SmithKline*
- 5:00 - 5:30 pm: **Human Antibodies: The State of the Art in Antibodies Using RIMMS**
Steve Chamow, Ph.D. - *Abgenix, Inc.*
- 7:00 - 10:00 pm: **Conference Banquet**

Thursday, May 10:

- 7:30 - 8:30 am: **Continental Breakfast** - Meeting Room Foyer
- 8:30 - 9:15 am: **Peptide Mapping of Monoclonal Antibodies: Practical Methodology and Applications to IND Proof-of-Structure and Identity / Comparability Testing**
Jacob S. Bongers, Ph.d. - *Glaxo SmithKline Pharmaceuticals*
- 9:15 - 10:00 am: **CHO or NS0? Case Study of Parallel Fast Track Development of a Monoclonal Antibody**
Kripa Ram, Ph.D. - *Biogen*
- 10:00 - 10:30 am: **Break - Meeting Room Foyer**
- 10:30 - 11:15 am: **LONZA Biologicals, plc.**
- 11:15 - 12:00 noon: **Panel Discussion**
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List of Exhibitors

Rockland Immuno-chemicals
Charles River Laboratories
Millipore
HyClone Laboratories, Inc.
Kendro Laboratory Products
Spectrum Laboratories, Inc. - Cellco
Applied BioSystems
Strategic Biosolutions
Sigma-Aldrich Fine Chemicals
BD Biosciences, Inc.
Serologicals Corp.
New Brunswick Scientific Co.
CropTech
Biovest
Corning Labware & Equipment - Labglass
Crucell
BioRad
JRH Biosciences
Siemens Moore
ViroMed Biosafety
BioWhittaker
Q-Biogene
TerraCell
Covance Research Products
Q-One Biotech, Inc.
MDS Pharma
Asahi Chemical Industry America
BIOPRO International, Inc.

Biovest
INTEGRA Biosciences
B. Braun Biotech International
Biomedical Resources
Chemunex, Inc.
Amersham Pharmacia Biotech Inc.
Invitrogen Corporation
Irvine Scientific Sales, Co., Inc.
BioPharm Magazine
Beckman Coulter, Inc.
TranXenoGen, Inc.
PALL BioPharmaceuticals
Wave Biotech
Lampire Biological Laboratories
Nova Biomedical
Refine Technologies
Formatech, Inc.
Cuno Filter Systems
Charter Medical, Ltd.
Westfalia Separator Inc.
BioReliance
EM Industries
Texcell
Crop Tech Corp.
MicroCal, LLC
Goodwin Biotech
North Carolina SRT, Inc.