

10th
ANNIVERSARY

The Waterside Conference

Process Development and Production Issues for Monoclonal & Recombinant Antibodies

Sunday, May 1

4:00–6:00 pm:

Registration and Welcome Reception, plus Exhibit & Poster Setup

Monday, May 2

7:00–8:00 am:

Registration and Continental Breakfast — *Exhibit Area Foyer*

8:00–8:30 am:

Introduction

Keith L. Carson — *Conference Chairman*

8:30–9:15 am:

Separation and Quantitation of Charge Variants in Monoclonal Antibody Drug Products

Jim Mo, Ph.D. — *Pfizer Inc.*

9:15–10:00 am:

Thinking Outside the Box: Consider High-Density Perfusion Processes for the Production of Biologicals

Sadettin Ozturk, Ph.D. — *Centocor, Inc.*

10:00–10:30 am:

Break — *Exhibit Area*

10:30–11:15 am:

Improving Platform Yields Through Media Optimization

Jian Wu, Ph.D. — *Amgen, Inc.*

11:15–12:00 noon:

Purification of a Difficult-to-Express Protein from Transgenic Milk

Nick Masiello — *GTC Biotherapeutics*

12:00–1:30 pm:

Lunch — *Exhibit Area*

1:30–2:15 pm:

Strategy for Characterization of Charged Variants of a Recombinant Monoclonal Antibody

Marian Eng — *Genentech, Inc.*

2:15–3:00 pm:

Process Change During Clinical Development

Amit Varma, Ph.D. — *MedImmune, Inc.*

3:00–3:30 pm:

Break — *Exhibit Area*

3:30–4:15 pm:

Early Development CMC Considerations for Monoclonal Antibodies

Kurt Brorson, Ph.D. — *FDA-CDER*

4:15–5:00 pm:

Formulation Optimization Studies Using Experimental Design Methods

Supriya Gupta, Ph.D. — *Protein Design Labs*

6:00–7:30 pm:

Reception — *Exhibit Area*

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Tuesday, May 3

- 7:30–8:30 am: **American Breakfast — Exhibit Area**
- 8:30–9:15 am: **Development of a Charge-Based Analytical Method Using Imaged Capillary Isoelectric Focusing**
George Wang, Ph.D. — *Chiron Corporation*
- 9:15–10:00 am: **CE Method Strategies for FIH Monoclonal Antibodies**
Jifeng Zhang, Ph.D. — *Amgen, Inc.*
- 10:00–10:30 am: **Break — Exhibit Area**
- 10:30–11:15 am: **The Quest for a Generic Industrial Purification Method for IgG**
Pete Gagnon — *Bio-Rad Laboratories*
- 11:15–12:00 noon: **Monitoring of Monoclonal Antibody Process Residuals with an Automated Electrochemiluminescence Immunoassay**
Marc Thorsteinsson, Ph.D. — *Merck & Company, Inc.*
- 12:00 noon–5:00 pm: **Free Afternoon with Recommended Group Activities**
- 7:00–10:00 pm: **Conference Banquet**



Wednesday, May 4

- 8:00–9:00 am: **Continental Breakfast — Exhibit Area**
- 9:00–10:00 am: **Technical Workshops I**
- 10:00–10:30 am: **Break — Exhibit Area**
- 10:30–12:00 noon: **Technical Workshops II**
- 12:00–1:30 pm: **Lunch — Exhibit Area**
- 1:30–2:15 pm: **Characterization of Half-Antibody in IgG4 Using LC/MS**
Yelena Lyubarskaya, Ph.D. — *Biogen Idec*
- 2:15–3:00 pm: **Commercial Implementation of Novel Affinity Ligands for Antibody and Antibody Fragment Purification**
Mark ten Haaft — *Biotechnology Application Centre*
- 3:00–3:30 pm: **Break — Exhibit Area (Exhibit & Poster Teardown at 3:30 pm)**
- 3:30–4:15 pm: **Expression Technologies: Evaluation and Optimization of Selection Systems for Therapeutic Monoclonal Antibody Production**
Dennis Kraichely, Ph.D. — *Centocor, Inc.*
- 4:15–5:00 pm: **Charge Heterogeneity in Therapeutic Monoclonal Antibodies — Defining Our Expectations?**
Asenath Rasmussen — *Pfizer Inc.*

