# RECOVERY OF BIOLOGICAL PRODUCTS XIII

**LOEWS LE CONCORDE HOTEL**
**QUEBEC CITY, QUEBEC**
**CANADA**

**22-27 JUNE 2008**

An International Conference

Sponsored by
The American Chemical Society
Division of Biochemical Technology

Conference Management Provided by:

Precision Meetings & Events
301 N. Fairfax St., Suite 301
Alexandria, VA 22314
USA

# Conference Chairs

Charles Glatz, Iowa State University, USA
Sam Guhan, Amgen, USA
Ann Lee, Genentech, Inc., USA

# Oral Session Chairs

Georges Belfort, Rensselaer Polytechnic Institute, United States
Charles Cooney, MIT, United States
Steve Cramer, Rensselaer Polytechnic Institute, United States
Stephen Drew, Science Partners, LLC, United States
Erik Fernandez, University of Virginia, United States
Chuck Goochee, Global Biologics Supply Chain (GBSC), a J&J company, United States
Jürgen Hubbuch, Research Center Jülich, Germany
Guenter Jagschies, GE Healthcare, Sweden
Brian Kelley, Genentech, Inc., United States
Steven Kozlowski, Food and Drug Administration, United States
Wolfgang Kuhne, Roche Diagnostics GmbH, Germany
Abraham Lenhoff, University of Delaware, United States
Paul Mensah, Pfizer, Inc., United States
Anton Middelberg, University of Queensland, Australia
Rhona O'Leary, Genentech, Inc., United States
Lars Pampel, Amgen, United States
Stuart Builder, Strategic Biodevelopment, United States
Theodore Randolph, University of Colorado, Boulder, United States
Andy Ramelmeier, BioMarin, United States
Neil Schauer, Millipore, United States
Abhinav Shukla, Bristol-Myers Squibb Company, United States
Ganesh Vedantham, Amgen, United States
Andrew Zydney, The Pennsylvania State University, United States

# Poster Session Chairs

Shishir Gadam, Genentech, Inc., USA
Charles Haynes, University of British Columbia, Canada
Maria-Regina Kula, Heinrich Heine University Dusseldorf, Germany

# Workshop Chairs

Matthew Croughan, Keck Graduate Institute, United States
Conan Fee, University of Canterbury, New Zealand
Uwe Gottschalk, Sartorius Stedim Biotech, Germany
Howard Levine, BioProcess Technology Consultants, United States
Todd Przybycien, Carnegie Mellon University, United States
Parviz Shamlou, Eli Lilly and Company, United States
Nigel Titchener-Hooker, University College London, United Kingdom
Miranda Yap, Biotechnology Processing Institute, Singapore

# SUNDAY, 22 JUNE 2008

**2:30 PM – 7:30 PM**
*Third Floor Foyer*
**REGISTRATION**

**5:30 PM - 6:30 PM**
*Third Floor Foyer*
**OPENING RECEPTION**

**6:30 PM – 7:15 PM**
*Grand Ballroom*
**OPENING DINNER**

**7:30 PM – 9:00 PM**
*Grand Ballroom*
**WELCOME REMARKS & INTRODUCTION TO KEYNOTE PRESENTATION**

New Types of Biopharmaceuticals: Exploiting the Therapeutic Potential of Human Stem Cells and Treating Human Cancers
*Harvey Lodish (MIT, United States)*

# MONDAY, 23 JUNE 2008

**7:00 AM – 8:00 AM**
*L'Astral*
**BREAKFAST**

**8:00 AM - 10:00 AM**
*Grand Ballroom*
**INTEGRATING BIOLOGY INTO BIOPROCESSING I**

***Session Chairs***: *Charles Cooney* (MIT, United States); *Stephen Drew* (Science Partners, LLC, United States)

Purification Processes: Sorting Out the Good, the Bad and the Ugly
*Anthony Mire-Sluis (Amgen, United States)*

Glycosylation Engineering of the Yeast *P. Pastoris* to Produce Therapeutic Protein
*Huijuan Li (Merck & Co., Inc., United States)*

Development And Process Integration: Enhancing Biopharmaceutical Productivity And Performance
*Mark Hardy (Wyeth BioPharma, United States)*

**10:00 AM – 10:30 AM**
*Ballroom Foyer & Leduc / Fortin*
**BREAK**

**10:30 AM - 12:30 PM**
*Grand Ballroom*
**BREAKTHROUGHS IN SEPARATIONS I**

***Session Chairs:*** *Georges Belfort* (Rensselaer Polytechnic Institute United States); *Andy Ramelmeier (*BioMarin, United States)

Connecting Protein Structure Perturbations on Hydrophobic Separations Media to Protein Physical Properties
*Todd Przybycien (Carnegie Mellon University, United States)*

Strategies for Tuning AEX Tentacle Phases for a Desired Separation
*Charles Haynes (University of British Columbia, Canada)*

Separations Implications of Phase Behavior of Monoclonal Antibodies and Other Proteins
*Abraham Lenhoff (University of Delaware, United States)*

Clustering Charges Improves Ion-Exchange Adsorbent Selectivity -And- Some Immunoaffinity Complexes Become More Tightly Associated With Aging
*Richard Willson (University of Houston, United States)*

**12:30 PM – 1:00 PM**
*Ballroom Foyer & Leduc / Fortin*
**LUNCHEON (BOX LUNCHES)**

**1:00 PM - 6:30 PM**
Scheduled Activities

**6:45 PM – 8:00 PM**
*Place Montcalm*
**DINNER**

**8:00 PM - 10:00 PM**
*Grand Ballroom*
**PROTEIN-"X" INTERACTIONS**

***Session Chairs:*** *Guenter Jagschies* (GE Healthcare, Sweden); *Erik Fernandez* (University of Virginia, United States)

Intelligent Design of Multimodal and Chemically Selective Displacement Systems Using Protein Libraries, NMR, SPR and Multi-Scale Simulations
*Steve Cramer (Rensselaer Polytechnic Institute, United States)*

Coexpression of an Unstable Fc-Fusion Protein With the Receptor Ligand to Generate a More Stable Product Feedstream Provides a New Set of Purification Challenges
*Scott Tobler (Wyeth BioPharma, United States)*

PEG Precipitation for Recovery of an IgG Monoclonal Antibody From Cell Culture Supernatant: Technologies to Develop High Throughput Methods for Process Scouting.
*Carol Knevelman (Lonza Biologics, United Kingdom)*

Effects of Temperature and Osmolytes on Dissociation of Protein Aggregates
*Christopher Roberts (University of Delaware, United States)*

# TUESDAY, 24 JUNE 2008

**7:00 AM – 8:00 AM**
*L'Astral*
**BREAKFAST**

**8:00 AM - 10:00 AM**
*Grand Ballroom*
**INTEGRATING BIOLOGY INTO BIOPROCESSING II**

***Session Chairs**: Rhona O'Leary* (Genentech, Inc., United States);
*Abraham Lenhoff* (University of Delaware, United States)

Innovation and Challenges in Manufacturing Next-Generation Antibody-Drug Conjugates
*Allen Ebens* (Genentech, Inc., United States)

Protein Interactions For The Control of Virus-Like Particle Assembly in Cell-Free Downstream Reactors
*Anton Middelberg* (University of Queensland, Australia)

A Proteomics Approach to Better Process Understanding Including Upstream and Downstream Integration
*Gunnar Malmquist* (GE Healthcare, Sweden)

A System for Remodeling the Carbohydrates on Recombinant Human Glucocerebrosidase
*Frank Riske,* Genzyme Corporation, United States

**10:00 AM – 10:30 AM**
*Ballroom Foyer & Leduc / Fortin*
**BREAK**

**10:30 AM - 12:30 PM**
*Grand Ballroom*
**BREAKTHROUGHS IN SEPARATIONS II**

***Session Chairs**: Abhinav Shukla* (Bristol-Myers Squibb Company, United States);
*Andrew Zydney* (The Pennsylvania State University, United States)

Purification of hIgG Using Small Peptide Ligand Affinity Chromatography
*Ruben Carbonell* (North Carolina State University, United States)

Protein Refolding by Means of Gradient Chromatography
*Marcel Ottens* (Delft University of Technology, Netherlands)

Technology Development for Purification of 10g/L titer Antibody Processes
*Jonathan Coffman* (Wyeth BioPharma, United States)

Recent Investigations of pH-Responsive HIC Media
*Ronnie Palmgren* (GE Healthcare, Sweden)

**12:30 PM – 1:30 PM**
*Jean-Paul Lemieux & Galerie*
**LUNCHEON**

**2:00 PM - 5:30 PM**
Team Activity

**6:00 PM – 7:30 PM**
*Place Montcalm*
**DINNER**

**7:30 PM - 9:30 PM**
*Grand Ballroom*
**NON-CHROMATOGRAPHIC SEPARATIONS**

***Session Chairs:** Anton Middelberg* (University of Queensland Australia); *Wolfgang Kuhne* (Roche Diagnostics GmbH Germany)

A Fundamental Understanding of Membrane Adsorber Technology
*Michael Phillips* (Millipore, United States)

Selective Precipitation-Assisted Recovery of Immunoglobulins From Bovine Serum and CHO Cell Supernatant Using Crossflow Microfiltration
*Georges Belfort* (Rensselaer Polytechnic Institute, United States)

Can Downstream Handle 5 G/L: Selective Precipitation of Monoclonal Antibodies versus Traditional Protein A Capture
*Robert Gronke* (Biogen Idec, United States)

New Hybrid Process for Bioproduct Isolation by Magnetic Micro-adsorbents and Magnetically Enhanced Aqueous Two-phase Partitioning
*Matthias Franzreb* (Forschungszentrum Karlsruhe, Germany)

# Wednesday, 25 JUNE 2008

**7:00 AM – 8:00 AM**
*L'Astral*
**BREAKFAST**

**8:00 AM - 10:00 AM**
*Grand Ballroom*
**INTEGRATION OF UPSTREAM & DOWNSTREAM**

***Session Chairs:*** *Lars Pampel* (Amgen, United States); *Jürgen Hubbuch* (Research Center, Jülich Germany)

Integration of Fermentation and Downstream Processing for the Production of L-Phenylalanine
*Emile van de Sandt* (DSM, Netherlands)

A Holistic Approach at Improving Upstream Feed Stock to Downstream Operations: Integration of Mammalian Cell Culture Operations
*Yinges Yigzaw* (Amgen, United States)

Industrial-Scale Membrane Chromatography for Rapid Capture of Complex Protein Drugs from Continuous Perfusion Culture
*Jens Vogel* (Bayer Healthcare, United States)

Challenges and Opportunities for Integrated Fast Track Process Development Concepts
*Dorothee Ambrosius* (Boehringer Ingelheim Pharma GmbH & Co. KG, Germany)

**10:00 AM – 10:30 AM**
*Ballroom Foyer & Leduc / Fortin*
**BREAK**

**10:30 AM - 12:30 PM**
*Suzor-Cote, Ballroom Foyer & Leduc/ Fortin*
**POSTER SESSION I**

***Session Chairs***: *Maria-Regina Kula* (Heinrich Heine University, Dusseldorf Germany);
*Shishir Gadam* (Genentech, Inc., United States); *Charles Haynes* (University of British Columbia, Canada)

**A1** Case Study: Fitting a Difficult Monoclonal Antibody into a Platform Process While Maintaining Timelines
*Elsie DiBella* (Centocor, United States)

**A3** 25 Years of Progress In Clinical Protein Production From Recombinant Cho Cell Culture: Impact On Batch Size
*Matthew Croughan* (Keck Graduate Institute, United States)

**A5** Challenges In Technology Transfer: Motavizumab Case Study
*P. David Robbins* (MedImmune, Inc., United States)

**B1** Purification of Supercoiled Plasmids Using Ultrafiltration
*Andrew Zydney* (The Pennsylvania State University, United States)

**B3** Effect of Membrane Pleating Upon Sterile Cartridge Performance
*Andrew Brown* (University College London, United Kingdom)

**B5** Scaling Up Filtration Processes During Downstream Processing
*Ralf Kuriyel* (Pall Life Sciences, United States)

**C1** ThioMAb Purification Challenges: Removing Triple Light Chain Product Variants
*Matthew Hutchinson* (Genentech, Inc., United States)

**C3** Case Study for Formulation of a Conjugate Vaccine

*Shwu Maan Lee* (Baxter, United States)

**D3** Removal of Prion Infectivity From Blood- and Plasma-Derived Products
*Patrick Gurgel* (ProMetic Life Sciences Inc., Canada)

**D5** Advances In Downstream Process Development and Manufacturing To Accommodate PER.C6®, A High Cell Density and Productivity Cell Line
*Gregory Zarbis-Papastoitsis* (PERCIVIA, LLC, United States)

**E1** Demonstration of the Utility and Feasibility of UVC Treatment for Viral Risk Mitigation in Biotechnology Applications
*Roger A. Hart* (Amgen, United States)

**E3** Heat Inactivation of Protease During Downstream Processing of a Fusion Protein Enables Purification of a Stable Bulk Drug Substance
*Peter Lambooy* (Eli Lilly and Company, United States)

**E5** Building Quality by Design Into a Late Stage Antibody Process
*John Pieracci* (Biogen Idec, United States)

**F1** The Effect of Arginine on Protein-Protein Interactions
*Robin Curtis* (University of Manchester, UK, United Kingdom)

**F3** Predicting Retention and Unfolding in Hydrophobic Interaction Chromatography Using a Statistical Mechanical Ensemble Model of Protein Structure
*Erik Fernandez* (University of Virginia, United States)

**F5** Model-Based Methodology For Robust Design And Process Validation of Preparative Chromatography
*Marcus Degerman* (Lund University, Sweden)

**G1** A Nanoparticle-Based Assay For Protein Formulation
*Peter Tessier* (Rensselaer Polytechnic Institute, United States)

**G3** Multilayered - Multifunctional Chromatography Matrices For Improved Downstream Processing
*Owen R.T. Thomas* (University of Birmingham UK, United Kingdom)

**H1** Separation of Free PEG from a PEG-Protein Conjugate of High Molecular Weight
*Nick Zecherle* (Biomarin Pharmaceutical, Inc., United States)

**H3** Chromatographic Separation Behavior of Pegylated Proteins in Relation to Their Physical and Biochemical Properties
*Shuichi Yamamoto* (Yamaguchi University, Japan)

**H5** Polyethyleneimine Precipitation vs. Anion Exchange Chromatography and Their Impacts in Subsequent Steps of Purification of an Acidic Protein From Transgenic Tobacco
*Chenming (Mike) Zhang* (Virginia Tech, United States)

**H7** Primary Recovery Options for MAb Purification : Evolution and Scale-up of a Flexible Platform Process
*David Roush* (Merck & Co., Inc., United States), *presented by Thomas Linden*

**J1** Optimizing a Mammalian Cell Culture Harvest Process: Using an Integrated Approach to Reduce Costs and Improve Process Consistency and Performance
*David Peers* (Genentech, Inc., United States)

**J3** Selective Precipitation Using Polyelectrolytes: Moving Towards Non-Chromatographic Purification of Monoclonal Antibodies
*Paul McDonald* (Genentech, Inc., United States)

**J5** Intensified Processes for the Purification of Proteins from Inclusion Bodies Using Integrated Expanded Bed Adsorption and On-column Refolding

*Howard Chase* (University of Cambridge, United Kingdom)

**K1** Continuous Recovery of Proteins Using Large-Scale Multicolumn EBA Chromatography Techology
*Marc Bisschops* (Xendo, Netherlands)

**K3** Predictive Models for Optimal Chromatography Conditions from 96-well plates and Verification in Small Columns
*Sydney Hoeltzli* (Pfizer, Inc., United States)
**K5** Optimization of High Throughput Process Optimization
*Eric von Lieres* (Research Center Jülich, Germany)

**L1** Mixed-Matrix Membrane Absorber Technology for the Separation of Therapeutic Proteins
*Michel Eppink* (NV Organon, Netherlands)

**L3** New Cation Exchange Sorbents for the Purification of Antibodies
*Heiner Graalfs* (Merck KGaA, Germany)

**L5** Improving Process Development Using Displacement Chromatography to Enhance Impurity Detection
*Barry Haymore* (SACHEM Inc, United States)

**L7** Induced Ph Gradients and Protein Separation On Unosphere S Cation Exchange Resin
*Mark Snyder* (Bio-Rad Laboratories, United States)

**L9** Purification of Peptides And Small Proteins By Means of Reversed Phase/Weak Anion Exchange Mixed Mode Chromatography
*Achim Schwaemmle* (Merck KGaA, Germany)

**L11** Membrane Adsorbers for the Primary Capture Step In Antibody Manufacturing
*Giulio Sarti* (University of Bologna, Italy)
**L13** Effective Pore Diameter Optimization Positively Affects the Preparative Purification of Insulin
*Timothy OMara* (Fuji Silysia Chemical SA, United States)

**12:30 PM – 1:30 PM**
*Jean-Paul Lemieux & Galerie*
**LUNCHEON**

**2:00 PM - 4:00 PM**
*Borduas*
**WORKSHOP I: IMPROVING THROUGHPUT**

***Session Chairs***: *Uwe Gottschalk* (Sartorius Stedim Biotech, Germany); *Nigel Titchener-Hooker* (University College London, United Kingdom)

Development of Next Generation Purification to Address High Titer Cell Culture for Monoclonal Antibodies
*Takashi Ishihara* (Kirin Pharma Company Limited, Japan)

Extending the Efficiency of Cation Exchange Bioseparations by Novel Approach for High Capacity Humabs Manufacturing
*Alahari Arunakumari* (Medarex, Inc., United States)

Meeting the Challenges of Large Scale Chromatography
*Ivars Bemberis* (Chisso Corporation, United States)

Process Portability to Fit a Diverse Manufacturing Network
*Jean Bender* (Genentech, Inc., United States)

Integration of Alternative Bioseparation Techniques into Platform Biomanufacturing Processes
*Karol M. Lacki* (GE Healthcare Biosciences, Sweden)

**2:00 PM - 4:00 PM**
*Krieghoff 1*
**WORKSHOP II: NEW PRODUCT TYPES - PNDUSTRY DISLOCATION**

***Session Chairs***: *Howard Levine* (BioProcess Technology Consultants, United States); *Miranda Yap* (Biotechnology Processing Institute, Singapore)
Development of A Platform Purification Biotechnological Production and Non-Chromatographic Recovery of Peptides
*Waltraud Kaar* (University of Queensland, Australia)

High Throughput Purification Process for Plasmid DNA
*Miladys Limonta* (Center for Genetic Engenering and Biotechnology, Cuba)

Process for Adenovirus
*Marcel de Vocht* (Crucell Holland BV, Netherlands)

The Promise and Challenges of RNA Interference
*Jason Murphy* (Merck & Co., Inc., United States), *presented by Richard Willson*

Stem Cell Separation: A Bottleneck in Stem Cell Therapy
*Anne Tscheliessnig* (Biotechnology Processing Institute, Singapore)

**2:00 PM - 4:00 PM**
*Krieghoff 2*
**WORKSHOP III: NEW INITIATIVES IN BIOPROCESS TECHNOLOGY EDUCATION**

***Session Chairs:*** *Todd Przybycien (*Carnegie Mellon University, United States); *Matthew Croughan* (Keck Graduate Institute, United States)

GMP Process-Scale Bioseparation Courses at the North Carolina State University Biomanufacturing Training and Education Center (BTEC)
*Gary Gilleskie* (North Carolina State University, United States)

Enhancing Traditional Chemical Engineering Curricula with a Web-Based Problem/Solution Repository
*Erik Fernandez* (University of Virginia, United States)

Biochemical Engineering Undergraduate and Graduate Education-Meeting Present Needs and Training Future Leaders
*Wei-Shou Hu* (University of Minnesota, United States)

Charting the Needs and Realities of the Undergraduate Bioengineering Curriculum
*Robert Linsenmeier* (Northwestern University, United States)

**2:00 PM - 4:00 PM**
*Pilot*
**WORKSHOP IV: TECHNOLOGIES OF THE FUTURE**

***Session Chairs***: *Parviz Shamlou* (Eli Lilly and Company, United States); *Conan Fee* (University of Canterbury, New Zealand)

Highly Sensitive Biosensor Assays for Monitoring Impurities In Protein Separation Processes. Assay of Endotoxin, Host Cell Proteins, Leaking Affinity Ligands etc. Using a Capacitive Biosensor
*Bo Mattiasson* (University of Lund, Sweden)

Single Use TFF Operations in Bioprocessing Applications
*Jon Petrone* (Pall Life Sciences, United States)

Miniturization and Automation of a Complete Chromatographic Process for the Purification Of mAB
*Jürgen Hubbuch (*Research Center Jülich, Germany)

Implementation of Emerging Technologies to Achieve a Simplified MAb Purification Process
*Martha Tse* (Genentech, Inc., United States)

Disposable Adsorption Systems for Monoclonal Antibody Processing: Practical, Scaleable Operations For Multi-Product Facilities.
*Rob Noel* (UpFront Chromatography A/S, Denmark)

**4:30 PM – 6:30 PM**
*Grand Ballroom*
**INDUSTRIAL CASE STUDIES I**

***Session Chairs***: *Paul Mensah* (Pfizer, Inc., United States); *Brian Kelley* (Genentech, Inc. United States)

Flexible Solutions Within a Templated Process Development Paradigm: Of Saints & Sinners
*Sanchayita Ghose* (Bristol-Myers Squibb Company, United States)

Case Study: How to Develop a 1-Ton Microbial Protein Process, Even When the World is Not Ready to Manufacture It
*Joseph Shultz* (Amgen, United States)

Process Development for the Purification of Virus-Like Particles: Case Studies on the Maturation of a Process Platform
*Thomas Linden* (Merck & Co., Inc., United States)

7:30 PM – 10:30PM
**DINE-AROUND**

# THURSDAY, 26 JUNE 2008

**7:00 AM – 8:00 AM**
*L'Astral*
**BREAKFAST**

**8:00 AM - 10:00 AM**
*Grand Ballroom*
**QUALITY BY DESIGN**

***Session Chairs***:
*Ganesh Vedantham* (Amgen, United States);
*Steven Kozlowski* (Food and Drug Administration, United States)

Introduction & Regulatory Perspective on QbD
*Steven Kozlowski (*Food and Drug Administration, United States)

Quality by Design: Impact of Quality Attribute Behavior on Process Design Space
*Duane Bonam (*Amgen, United States)

Using a Risk Assessment Process to Select Critical Product Quality Attributes
*Matthew Dickson (*MedImmune, Inc., United States)

QbD: Integrating Regulatory Innovation With Good Science
*Gregory Blank (*Genentech, Inc., United States)

**10:00 AM – 10:30 AM**
*Ballroom Foyer & Leduc / Fortin*
**BREAK**

**10:30 AM - 12:30 PM**
*Suzor-Cote, Ballroom Foyer & Leduc/ Fortin*
**POSTER SESSION II**

***Session Chairs:*** *Maria-Regina Kula* (Heinrich Heine University, Dusseldorf, Germany);
*Shishir Gadam* (Genentech, Inc., United States);
*Charles Haynes* (University of British Columbia, Canada)

**A2** Downstream Processing of an Antibody-Based Biologic Produced at 15,000 L Scale: Purification of Drug Substance from a Feedstock Containing Fifty Percent Product-Related Impurities
*David Evans* (Biogen Idec, United States)

**A4** Accelerated Development of a Downstream Purification Process for a Production of a Monoclonal Antibody: A Case Study
*Guenter Jagschies* (GE Healthcare, Sweden)

**A6** Engineering of Batch and Continuous Refolding Processes Using Autoprotease Fusion Proteins
*Alois Jungbauer* (University of Natural Resources, Austria)

**B2** Diafiltration Performance in the High Concentration UF/DF for a Monoclonal Antibody
*Robert Luo* (Human Genome Sciences, Inc., United States)

**B4** Theoretical Analysis of the Effects of Asymmetric Membrane Structure on Fouling During Microfiltration
*Chia-Chi Ho* (University of Cincinnati, United States)

**B6** Scaling of Depth Filtration for Cell Culture Clarification
*Herbert Lutz* (Millipore, United States)

**C4** Producing and Purifying An *E. coli* Derived One-Armed Antibody
*Josefine Persson* (Genentech, Inc., United States)

**C6** In-line Buffer Dilution: An Operational, Economic and Regulatory Evaluation
*Lou Bellafiore* (TechniKrom Inc., United States)

**D2** RUNspike, an Alternative Virus Spiking Strategy
*Paul Genest* (Millipore, United States)

**D4** Engineering of a Scalable Purification for IgMs Directed Against Undifferentiated Human Embryonic Stem Cells
*Anne Tscheliessnig* (Bioprocessing Technology Institute, Singapore)

**D6** Development and Utilization of Cost of Goods Models for Biologics Manufacturing
*Curran Simpson* (Human Genome Sciences, Inc., United States)

**E2** Novel Virus Clearance Platform Utilizing Three Orthogonal Strategies "Early-on" in Biopharmaceutical Purification
*Suma Ray* (Sartorius Stedim Biotech, India)

**E4** An Engineering Approach for Estimating Clearance of Impurities in Purification Processes
*Kent Goklen* (Cornell University United States)

**E6** Process Intensification and Sustainability in Biopharmaceutical Purification: A Case for Advanced PATs
*Milton T W Hearn* (Monash University, Australia)

**F2** Predictive Chromatographic Simulations for the Optimization of Recovery and Aggregate Clearance During the Capture of Therapeutic Monoclonal Antibodies
*Mark Teeters* (Centocor, United States)

**F4** Use of Simulation for Robustness Analysis of an Industrial Ion Exchange Step
*Thomas Hansen* (Novo Nordisk A/S, Denmark)

**G2** Chimeric Simian: Human Immunodeficiency Virus-Like Nanoparticle from HEK293 cell cultures.
*Guilherme Ferreira* (University of Algarve, Portugal)

**H2** Measurement of Electrostatic Interactions of PEGylated Proteins Using a Novel Multi-Channel Surface Plasmon Resonance Technique
*Conan Fee* (University of Canterbury, New Zealand)

**H4** Application of Design Space Methodology to a Multi-scale Centrifugation Harvest Operation with pH Induced Impurity Precipitation and Flocculation
*Lynn Conley* (Biogen Idec, United States)

**H6** Characterization of Proteins from Plants: Aqueous Two-Phase System-Based Bioengineering Strategies
*Marco Rito-Palomares* (ITESM Biotechnology Center, Mexico)

**H8** The Development of a Scalable Process to Release Periplasmic Proteins Using Osmotic Shock
*Anant Patkar* (The Dow Chemical Company, United States)

**J2** Back To The Future: The Use of Batch Adsorption in the Recovery of Antibody Fragments From An Unclarified *E. coli* Lysate
*Nigel Titchener-Hooker* (University College London, United Kingdom)

**J4** Recovery and Non-chromatographic Purification of Soybean Bowman-Birk-Inhibitor (sBBI) from a Fusion Protein System
*Michael Bodo* (Genencor International, United States)

**J6** Expanded Bed Capture: Implementation From Laboratory To Full Scale
*John Liddell* (Avecia Biologics, United Kingdom)

**K4** RAPPTorTM: A New Technology For High Throughput Downstream Development
*Franz Nothelfer* (Boehringer Ingelheim Pharma GmbH & Co. KG, Germany)

**K6** Small Scale Automated High Throughput Chromatographic Separations in Process Development, In-Process Monitoring and Validation of Biopharmaceutical Production
*Jürgen Friedle* (Atoll GmbH, Germany)

**L2** Disposable-Format Simulated Moving Bed Systems for Biopharmaceutical Purification
*Scott Fulton* (BioSystem Development, United States)

**L4** Investigations of Non-ideal Peak Profiles in Preparative Chromatographic Processes
*Arthur Hewig* (Amgen, United States)

**L6** Scale-up of Membrane Chromatography for Biopharmaceutical Applications
*Ajay Lajmi* (Pall Life Sciences, United States)

**L8** Capacity, Productivity and Cost of Operation Characterization of a Novel High Performance Protein A Chromatography Media
*Chen Wang* (Millipore, United States)

**L10** Affinity Chromatography Using Camelid Single Domain Antibodies, From Technology Platform To Purification Products
*Laurens Sierkstra* (BAC BV, Netherlands)

**L12** Implementation of Monoliths for Purification of Large Plasmids and Viruses
*Ales Podgornik* (BIA Separations d.o.o., Slovenia)

**L14** Application of Anion Exchange Resins for Chromatographic Separation of Human Plasma Proteins
*Egbert Mueller* (Tosoh Bioscience GmbH, Germany)

**12:30 PM – 1:30 PM**
*Jean-Paul Lemieux & Galerie*
***LUNCHEON***

**1:45 PM - 3:15 PM**
*Grand Ballroom*
**INDUSTRIAL CASE STUDIES II**
***Session Chairs***:

*Stuart Builder* (Strategic Biodevelopment United States); *Chuck Goochee (*Global Biologics Supply Chain (GBSC), a J&J company, United States)

T3: Technology Transfer Across Time
*Christine Mendoza (*Amylin Pharmaceuticals, Inc., United States)

ETC216: From In-License to CMO with Aggressive Technology Transfer and Manufacturing Timeline
*Sa Ho (*Pfizer, Inc., United States

Post Phase III Recovery Process Changes for an Antibody Fragment Expressed in *E. coli*: Lucentis® Case Study
*Michelle Butler (*Genentech, Inc., United States)

**3:30 PM – 5:00 PM**
**SCHEDULED ACTIVITIES**

**6:00 PM - 7:30 PM**
*National Art Museum of Quebec*
**CLOSING RECEPTION**

**7:30 PM - 10:00 PM**
*National Art Museum of Quebec*
**CLOSING BANQUET**

# FRIDAY, 27 JUNE 2008

**7:00 AM – 8:00 AM**
*L'Astral*
**BREAKFAST**

**8:00 AM - 10:00 AM**
*Grand Ballroom*
**INTEGRATION OF DOWNSTREAM & FORMULATION**

***Session Chairs***: *Theodore Randolph (*University of Colorado, Boulder, United States); *Neil Schauer (*Millipore, United States)

Effects of the Manufacturing Process on Protein Stability
*Bruce Kerwin (*Amgen, United States)

Improved Output and Quality At The Interface of DSP and Final Formulation
*Gerhard Winter (*Lugwig Maximilians Universitat Muchen, Germany)

Reduction of Protein Aggregates in Process Development Using High Hydrostatic Pressure
*David Zeng (*Barofold Inc, United States)

Formulation Strategy and High Temperature UF to Achieve High Concentration rhuMAbs
*Charles Winter* (Genentech, Inc., United States)

**10:00 AM – 10:15 AM**
*Ballroom Foyer & Leduc / Fortin*
**BREAK**

**10:15 AM - 11:45 AM**
*Grand Ballroom*
**SHORT REPORT OUT WITH AUDIENCE RESPONSE ON POSTERS & WORKSHOPS**

***Session Chair***: *Steve Cramer (*Rensselaer Polytechnic Institute, United States)

**11:45 AM - 12:00 PM**
**CLOSING REMARKS & ADJOURN**

**12:00 PM – 1:00 PM**
*Ballroom Foyer*
**LUNCHEON**