RXV

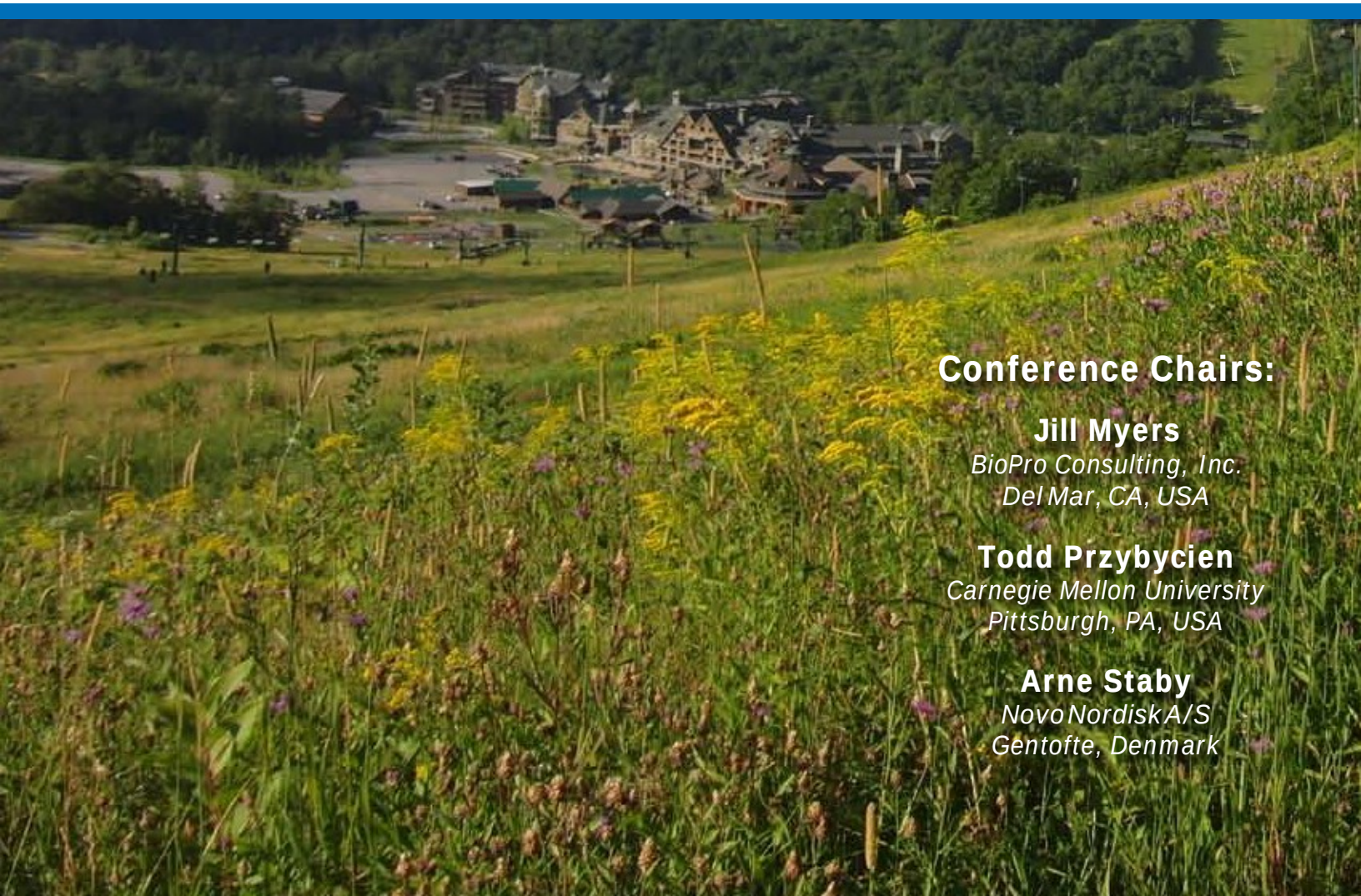
Recovery of Biological Products

Sustainability
Stowe, VT
2012

Program, Abstracts and Conference Information

July 29 – August 3, 2012

Stowe Mountain Lodge
Stowe, Vermont



Conference Chairs:

Jill Myers
BioPro Consulting, Inc.
Del Mar, CA, USA

Todd Przybycien
Carnegie Mellon University
Pittsburgh, PA, USA

Arne Staby
Novo Nordisk A/S
Gentofte, Denmark

RECOVERY OF BIOLOGICAL PRODUCTS XV

STOWE MOUNTAIN LODGE
STOWE, VERMONT
USA

JULY 29 – AUGUST 3, 2012

An International Conference

Sponsored by
The American Chemical Society
Division of Biochemical Technology

Conference Management Provided by:

Precision Meetings & Events, Inc.
301 N. Fairfax St., Suite 104
Alexandria, VA 22314
USA

CONFERENCE CHAIRS

Jill Myers, BioPro Consulting, Inc, United States
Todd Przybycien, Carnegie Mellon University, United States
Arne Staby, Novo Nordisk A/S, Denmark

ORAL SESSION CHAIRS

Haleh Ahmadian, Novo Nordisk A/S, Denmark
Dorothee Ambrosius, Boehringer Ingelheim Pharma GmbH, Germany
Jean Bender, MedImmune, United States
Ruben Carbonell, North Carolina State University, United States
Jonathan Coffman, Pfizer, Inc., United States
John Curling, John Curling Consulting AB, Sweden
Suzanne Farid, University College London, United Kingdom
Victor Goetz, ImClone Systems, United States
Klaus Graumann, Sandoz, Austria
Milton T W Hearn, Monash University, Australia
Jürgen Hubbuch, Karlsruhe Institute of Technology, Germany
Günter Jagschies, GE Healthcare, Sweden
Janus Krarup, Novo Nordisk A/S, Denmark
Maria-Regina Kula, Heinrich Heine University Düsseldorf, Germany
Philip Lester, Genentech, Inc., United States
Anton Middelberg, University of Queensland, Australia
Egbert Müller, Tosoh Bioscience GmbH, Germany
Marcel Ottens, Delft University of Technology, Netherlands
Lars Pampel, Novartis Biologics, Switzerland
Hari Pujar, Merck & Co., Inc., United States
Tom Ransohoff, BioProcess Technology Consultants, United States
Joseph Shultz, Amgen, United States
Jörg Thömmes, Biogen Idec, United States
Ganesh Vedantham, Amgen, United States
Victor Vinci, Eli Lilly and Company, United States
Jens Vogel, Boehringer Ingelheim Pharma GmbH & Co. KG, United States
Suresh Vunnum, Amgen, United States

WORKSHOP SESSION CHAIRS

Kurt Brorson, Food and Drug Administration, United States
Erik Fouts, Biomarin Pharmaceutical, Inc., United States
Rainer Hahn, University of Natural Resources, Austria
Mike Hoare, University College London, United Kingdom
Anurag Rathore, Indian Institute of Technology Delhi, India
David Robbins, MedImmune, Inc., United States
Richard Siegel, Janssen R&D, LLC, United States
Andrew Zydney, The Pennsylvania State University, United States

POSTER SESSION CHAIRS

Steve Cramer, Rensselaer Polytechnic Institute, United States
Charles Haynes, University of British Columbia, Canada
Brian Kelley, Genentech, Inc., United States

SCHEDULE AT-A-GLANCE

July 29 Sunday	July 30 Monday	July 31 Tuesday	August 1 Wednesday	August 2 Thursday	August 3 Friday
	7:00 – 8:00 AM Breakfast *Over Easy Plaza*	**7:00 – 8:00 AM** Breakfast *Over Easy Plaza*	**7:00 – 8:00 AM** Breakfast *Over Easy Plaza*	**7:00 – 8:00 AM** Breakfast *Over Easy Plaza*	**7:00 – 8:00 AM** Breakfast *Over Easy Plaza*
11:00 AM Registration Opens *Spruce Camp*	**8:00 – 10:00 AM** Structure-Processing Relationships for Biologicals *Spruce Camp – Great Room*	**8:00 – 10:00 AM** The Shrinking Footprint – Sustainability in Multiproduct Facilities and Design *Spruce Camp – Great Room*	**8:00 – 10:00 AM** Antibodies Behaving Badly in a Post Platform World II *Spruce Camp – Great Room*	**8:00 – 10:00 AM** Continuous Improvement in Bioprocessing by Continuous Bioprocessing *Spruce Camp – Great Room*	Conference Concludes
	10:00 – 10:30 AM Refreshments *Spruce Camp Terrace*	**10:00 – 10:30 AM** Refreshments *Spruce Camp Terrace*	**10:00 – 10:30 AM** Refreshments *Spruce Camp Terrace*	**10:00 -10:30 AM** Refreshments *Spruce Camp Terrace*	
	10:30 AM – 12:30 PM Automation in BioProcess Development *Spruce Camp – Great Room*	**10:30 – 12:00 PM** Next-Gen Chromatographic Purification Ready for Plug-&-Play *Spruce Camp – Great Room*	**10:30 AM – 12:30 PM** Model-based QbD – Opportunities to Quit Being Dull *Spruce Camp – Great Room*	**10:30 AM – 12:30 PM** Non-Antibody Proteins Behaving Badly in a Pre Platform World *Spruce Camp – Great Room*	
	12:30 PM Box Lunch *Over Easy Plaza*	**12:00 – 3:00 PM** Box Lunch (mountain top) *Cliff House*	**12:30 PM** Box Lunch *Over Easy Plaza*	**12:30 – 1:30 PM** Luncheon *Over Easy Plaza* Poster Breakdown **all posters must be down by 1:00 pm.*	
1:30 – 4:00 PM Refreshments *Spruce Camp Terrace* **Poster Set-up** *Spruce Camp – Great Room* _____ **3:30 – 5:30 PM** Opening remarks & Sustainability – The Future of Biopharmaceutical Processing *Spruce Camp – Great Room*	**1:00 – 6:00 PM** Activities (optional)	**3:00 – 5:00 PM** (2 parallel sessions) Non-Chromatographic Purification *Tamarack Ballroom C* Biological Product Purification – Beyond Proteins *Junior Ballroom* _____ **5:00 – 5:15 PM – break** *Tamarack Ballroom Foyer*	**1:00 – 6:00 PM** Activities (optional)	**1:30 – 3:00 PM** Biosimilars or Similar BioProcessing *Spruce Peak Performing Arts Center* **3:00 – 3:30 PM** Refreshments *Spruce Peak Performing Arts Center*	
5:30 – 6:30 PM Cocktails & Entertainment *Poolside*		**5:15 – 6:45 PM** (4 parallel sessions) Workshops *Tamarack Ballroom A, B, D, and E*		**3:30 – 5:30 PM** (R)Evolution in Downstream Processing *Spruce Peak Performing Arts Center*	
6:30 – 8:30 PM Welcome Dinner *Poolside*	**6:30 – 8:00 PM** Dinner *Over Easy Plaza*	**7:00 – 8:30 PM** Dinner *Over Easy Plaza*	**6:30 – 8:00 PM** Dinner *Over Easy Plaza*	**6:30 – 10:00 PM** Closing Banquet Entertainment *Spruce Camp – Great Room*	
8:30 – 10:00 PM Keynote Address Jerry Greenfield Co-founder of Ben and Jerry's Ice Cream *Spruce Peak Performing Arts Ctr*	**8:00 – 10:00 PM** Posters with Dessert *Spruce Camp – Great Room*	**8:30 – 10:00 PM** Antibodies Behaving Badly in a Post Platform World I *Spruce Camp – Great Room*	**8:00 – 10:00 PM** Posters with Dessert *Spruce Camp – Great Room*		

ORAL SESSIONS

Sustainability – The Future of Biopharmaceutical Processing

Session Chairs:
Jonathan Coffman, Pfizer, Inc., United States John Curling, John Curling Consulting AB, Sweden

#429) Defining Sustainability for Bioprocess Engineering
Valerie Patrick (Bayer Corp.)

#320) Green Chemistry and Engineering – New Tools to Achieve Greater Process Sustainability and Enhanced Productivity in BioManufacturing
Milton Hearn (Monash University)

#237) Thinking of Change; Addressing the Greatest Challenges to Meet the Future
Günter Jagschies (GE Healthcare), Eric Grund (GE Healthcare), *Karol Lacki (GE Healthcare)*

#313) Recombinant Protein Production in Barley Seeds
Auður Magnúsdóttir (ORF Genetics) Jón Már Björnsson (ORF Genetics) Lýður Erlendsson (ORF Genetics) Einar Mäntylä (ORF Genetics) Björn Örvar (ORF Genetics) Arna Rúnarsdóttir (ORF Genetics)

Structure-Processing Relationships for Biologicals

Session Chairs:
Milton T W Hearn, Monash University, Australia Marcel Ottens, Delft University of Technology, Netherlands

#351) Design and High-Throughput Analysis of Aggregation-Resistant, High-Affinity Antibodies
Peter Tessier (Rensselaer Polytechnic Institute)

#161) A Random Forest Approach to Prediction of Separation Performance

Charles Glatz (Iowa State University) Ryan Swanson (Iowa State University)

#375) Molecular Engineering of Multiple Weak Interactions for High Selectivity Protein Separations

Steve Cramer (Rensselaer Polytechnic Institute) Shekhar Garde (Rensselaer Polytechnic Institute) Melissa Holstein (Rensselaer Polytechnic Institute) Siddharth Parimal (Rensselaer Polytechnic Institute) James Woo (Rensselaer Polytechnic Institute)

#384) Assembly of Knob and Hole Bispecific Antibodies
Glen Giese (Genentech, Inc.) Josefine Persson (Genentech, Inc.) Ambrose Williams (Genentech, Inc.)

Automation in BioProcess Development

Session Chairs:
Haleh Ahmadian, Novo Nordisk A/S, Denmark
Jürgen Hubbuch, Karlsruhe Institute of Technology, Germany

#241) Rational and Fast Protein Purification Process Development – a Hybrid Experimental and Modeling Approach

Marcel Ottens (Delft University of Technology) Beckley K. Nfor (Delft University of Technology) Luuk A.M. Van der Wielen (Delft University of Technology) Peter D.E.M. Verhaert (Delft University of Technology)

#296) Fast Protein Analytics for HTE – Multivariate Calibration Minimizes Tradeoff between Speed and Information

Sigrid K. Hansen (Karlsruhe Institute of Technology) Patrick Diederich (Karlsruhe Institute of Technology) Jüprgen Hubbuch (Karlsruhe Institute of Technology) Stefan Oelmeier (Karlsruhe Institute of Technology) Erik Skibsted (Novo Nordisk A/S) Arne Staby (Novo Nordisk A/S)

#239) Smart Upscaling Translations of Purification Processes: Approach for Developing Purification Processes from Micro to Column Scale

Michel Eppink (Synthon) Guy de Roo (Synthon) Xiaonan Li (Synthon)

#252) Recovery of Proteins from Inclusion Bodies: The Development of an Automated Microscale Platform to Study the Effect of Upstream Conditions on Whole Process Performance

Gemma Ordidge (University College London) Paul Dalby (University College London) John Liddell (Fujifilm Diosynth Biotechnologies) Martina Micheletti (University College London)

The Shrinking Footprint - Sustainability in Multiproduct Facilities and Design

Session Chairs:
Tom Ransohoff, BioProcess Technology Consultants, United States Ganesh Vedantham, Amgen, United States

#321) Development of a Single Use Process Platform with Flexibility for Multiproduct CHO Cell and Baculovirus Expression at 1,000 L Scale in a GMP Manufacturing Facility

Stewart McNaull (Fujifilm Diosynth Biotechnologies) Scotty Bailey (Fujifilm Diosynth Biotechnologies) Kathy Chung (Fujifilm Diosynth Biotechnologies) Sharyn Farnsworth (Fujifilm Diosynth Biotechnologies) George Koch (Fujifilm Diosynth Biotechnologies) Michael Murray (Fujifilm Diosynth Biotechnologies) Gary Pelletier (Fujifilm Diosynth Biotechnologies) Clara Rangel (Fujifilm Diosynth Biotechnologies) Patrick Robertson (Fujifilm Diosynth Biotechnologies) Jonathan Sumy (Fujifilm Diosynth Biotechnologies)
Gayathri Vasudevan (Fujifilm Diosynth Biotechnologies) Charles Workman (Fujifilm Diosynth Biotechnologies)

#390) Implementation of a Highly Flexible Multi Product Downstream Processing Facility for Clinical Supply at Roche Penzberg

Boris Bieger (Roche Diagnostics GmbH) Wolfgang Kuhne (Roche Diagnostics GmbH) Josef Vinnemeier (Roche Diagnostics GmbH)

#112) Using Single-Use Technologies to Improve Speed to Clinic – A Case Study

Venkatesh Natarajan (Millipore) Elizabeth Goodrich (Millipore) Fred Mann (Millipore)

#175) Protein Reaction and Process Integration Optimization

Thomas Svenstrup (Novo Nordisk A/S)

Next-Gen Chromatographic Purification

Session Chairs:
Günter Jagschies, GE Healthcare, Sweden
Egbert Müller, Tosoh Bioscience GmbH, Germany

#194) Experimental Characterization of Capillary-Channelled Polymer Stationary Phases for the Purification of Large Biomolecules

Conan J. Fee (University of Canterbury) Simone Dimartino (University of Canterbury)
R. Kenneth Marcus (Clemson University) Daniel Momich (University of Canterbury) Abby J. Schadock-Hewitt (Clemson University)

#203) Continuous Chromatography in Clinical Manufacturing: The Economic and Environmental Impact

Suzanne Farid (University College London) Glen Bolton (Pfizer, Inc.)
Daniel Bracewell (University College London) Sa Ho (Pfizer, Inc.)
James Pollock (University College London)

#289) Addressing Future Purification Needs: Revisiting Old Concepts

Karol M. Lacki (GE Healthcare)
Bo-Lennart Johansson (GE Healthcare) John Joseph (GE Healthcare)
Jean-Luc Maloisel (GE Healthcare) Tobias Söderman (GE Healthcare)

Non-Chromatographic Purification – Ready for Plug-and-Play?

Session Chairs:
Philip Lester, Genentech, Inc., United States
Anton Middelberg, University of Queensland, Australia

#177) Harnessing the Benefits of Membrane Chromatography for Impurity Reduction in High Titre Monoclonal Antibody Production

Lee Allen (Lonza Biologics), Bruce McCafferty (Lonza Biologics), Mardon McFarlane (Lonza Biologics), Abdel Zemmar (Lonza Biologics)

#137) Aqueous Two-Phase Systems for Antibodies Purification: From Macro to Micro-Scale

Raquel Aires-Barros (Instituto Superior Técnico) Ana Azevedo (Instituto Superior Técnico)

#290) Process Development Balancing Solubility and Partitioning – Aqueous Two-Phase Extraction of Proteins

Stefan Oelmeier (Karlsruhe Institute of Technology)
Michael Dieterle (Boehringer Ingelheim Pharma GmbH & Co. KG) Florian Dismer (Karlsruhe Institute of Technology)
Jürgen Hubbuch (Karlsruhe Institute of Technology)
Michael Richter (Boehringer Ingelheim Pharma GmbH & Co. KG)

#244) Solvent Free Precipitation of Plasma Proteins

James Van Alstine (GE Healthcare Biosciences) Karol Łącki (GE Healthcare Biosciences)
Mikael Berg (GE Healthcare Biosciences) Johanna Kjörning (GE Healthcare Biosciences) Jamil Shanagar (GE Healthcare Biosciences)

Biological Product Purification – Beyond Proteins

Session Chairs:
Ruben Carbonell, North Carolina State University, United States
Hari Pujar, Merck & Co., Inc., United States

#178) Industrially Generated Red Blood Cells for Transfusion

Nik Willoughby (Heriot Watt University, Edinburgh, UK) Fiona Dempsey (Heriot Watt University, Edinburgh, UK) Jo Mountford (College of Medical, Veterinary & Life Sciences, University of Glasgow, Glasgow, UK.)

#392) Bridging the Gap to the Next Generation of Vaccines: What Will Be the Role of Chromatography?

Michael Laska (Merck & Co., Inc.)

#412) Continuous, Closed-System Fractionation and Isolation of Cell Culture Derived Platelets Using Deterministic Flow Fractionation

Charles Haynes (University of British Columbia) Dana Devine (University of British Columbia) Patrick Francis (University of British Columbia) Johan Innes (University of British Columbia)

#211) Bioprocessing of Bacterially-Expressed Viral Capsomeres for Rapid and Cheap Influenza Vaccination

Nani Wibowo (University of Queensland) Yap Pang Chuan (University of Queensland) Linda HL Lua (University of Queensland) Anton PJ Middelberg (University of Queensland)

Antibodies Behaving Badly in a Post-Platform World I

Session Chairs:
Dorothee Ambrosius, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
Victor Goetz, ImClone Systems, United States

#235) Stability of monoclonal antibodies in upstream processing conditions

Kurt Lang (Roche Diagnostics GmbH) Stefan Dengl (Roche Diagnostics GmbH) Friederike Hesse (Roche Diagnostics GmbH) Marc Wehmer (Roche Diagnostics GmbH)

#182) How to Evolve Inappropriate Antibodies for Production

Alexander Jacobi (Boehringer Ingelheim Pharma GmbH & Co. KG)

#254) Platform downstream processes for monoclonal antibody purification: Could platform be a decision tree?

Nihal Tugcu (Merck & Co., Inc.) Thomas Linden (Merck & Co., Inc.) Jennifer Pollard (Merck & Co., Inc.) David Roush (Merck & Co., Inc.)

Antibodies Behaving Badly in a Post-Platform World II

Session Chairs:
Dorothee Ambrosius, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
Victor Goetz, ImClone Systems, United States

#263) HIC with Mixed Electrolytes for MAb Purification

Egbert Müller (Tosoh Bioscience GmbH) Tim Schröder (Atoll GmbH)
Judith Vajda (Tosoh Bioscience GmbH)

#187) Development of an Effective Non-Platform Purification Process for a Monoclonal Antibody

John Bodek (Johnson & Johnson (Centocor))

#212) Impact of the Purification Process on Particle Formation and Particle Control in Monoclonal Antibody Products

Yuling Li (MedImmune, Inc.)
Daniel Callahan (MedImmune, Inc.) Bradford Stanley (MedImmune, Inc.)

#209) Trisulfides: A Significant Source of Variability in ADC Conjugations

Timothy Tully (Genentech, Inc.) Katherine Cumnock (Genentech, Inc.) Jeff Gorrell (Genentech, Inc.)
Matt Hutchinson (Genentech, Inc.) Fred Jacobson (Genentech, Inc.)

Model-based QbD – Opportunities to "Quit Being Dull"

Session Chairs:
Jean Bender, MedImmune, United States
Suzanne Farid, University College London, United Kingdom

#128) An Integrated Approach to the Application of QbD Principles During the Development and Technology Transfer of an Optimised Biotech Process
James Pierce (Pfizer, Inc.)

#323) From Data to Knowledge - A Model Based Approach to Designing High Throughput Experiments

Marcus Degerman (Lund University) Bernt Nilsson (Lund University) Matthias Wiendahl (Novo Nordisk A/S)

#92) Mechanistic Modeling and Linked Upstream-Downstream Design Space for Control and Optimization of Deamidation

In a Monoclonal Antibody

David Robbins (MedImmune, Inc.) Gisela Ferreira (MedImmune) Guillermo Miro-Quesada (MedImmune, Inc.) Kripa Ram (MedImmune, Inc.)

#188) Integration of Formulation Development, Equipment Design, and Process Development to Enable High Concentration Product Formulations

Suma Rao (Amgen) Eva Gefroh (Amgen) Steve Hunt (Amgen) Oliver Kaltenbrunner (Amgen)

Continuous Improvement in Bioprocessing by Continuous Bioprocessing

Session Chairs:
Lars Pampel, Novartis Biologics, Switzerland Joseph Shultz, Amgen, United States

#179) What Can Continuous Processing Do For You?

Mark Brower (Merck & Co., Inc.) Alexandra Buttke (Merck & Co., Inc.) Ying Hou (Merck & Co., Inc.) David Pollard (Merck & Co., Inc.)

#176) Development of Integrated Continuous Bioprocessing for Therapeutic Proteins

Frank Riske (Genzyme Corporation) Kevin Brower (Genzyme Corporation) Daniel Cummings (Genzyme Corporation) Rahul Godawat (Genzyme Corporation) Konstantin Konstantinov (Genzyme Corporation) Veena Warikoo (Genzyme Corporation)

#123) Improving Platform Flexibility Using SPTFF

Matthew Westoby (Biogen Idec) Alex Brinkmann (Biogen Idec)

#298) New Downstream Template for Continuous Mab Processing

Michael Phillips (EMD Millipore) Sven Andrecht (EMD Millipore) Kevin Galipeau (EMD Millipore) Christopher Gillespie (EMD Millipore) Mikhail Kozlov (EMD Millipore) Romas Skudas (EMD Millipore) Alex Xenopoulos (EMD Millipore)

Non-Antibody Proteins Behaving Badly in a Pre-Platform World

Session Chairs:
Janus Krarup, Novo Nordisk A/S, Denmark Victor Vinci, Eli Lilly and Company, United States

#360) Challenges in the Development of a One-Step Anion Exchange Chromatography Step for PEGylated Human Growth Hormone

Brandi Osborne (Pfizer, Inc.)

#85) Behavior of Chimeric Proteins and Challenges Associated With Generating Drug Substance

Peter Lambooy (Eli Lilly and Company)

312) Production and Characterization of Recombinant Circumsporozoite Protein: A Malaria Vaccine Candidate Utilizing the Pseudomonas fluorescens-based Pfēnex Expression TechnologyTM

Jeff Allen (Pfenex Inc.) Greg Cantin (Pfenex Inc.) Nicole Glenn (Pfenex Inc.) Ryan Haverstock (Pfenex Inc.) Steve Maki (Pfenex Inc.) Jerry Ngai (Pfenex Inc.) Jason Payne (Pfenex Inc.) Alex Stevens (Pfenex Inc.) James Ware (Pfenex Inc.)

#419) An Effective Self-Cleaving Tag Platform for Proteins Expressed in Mammalian Cells

David Wood (Ohio State University) Buyong Ma David Nellis

Biosimilars or Similar Bioprocessing?

Session Chairs:
Klaus Graumann, Sandoz, Austria
Jens Vogel, Boehringer Ingelheim Pharma GmbH & Co. KG, United States

#411) Next Steps in Developing the Nation's Biosimilars Program

Jeffrey Baker (Food and Drug Administration)

#311) Development and Manufacturing Aspects for Biosimilars

Klaus Graumann (Sandoz)

Point-Counter-Point Discussion
Brian Kelley (Genentech, Inc.) and *Tom Ransohoff (BioProcess Technology Consultants)*

(R)Evolution in Downstream Processing

Session Chairs:
Maria-Regina Kula, Heinrich Heine University Düsseldorf, Germany Jörg Thömmes, Biogen Idec, United States

#269) Process Evolution and Innovation in Plasma Protein Therapeutics

John Curling (John Curling Consulting AB)

#345) Development of Relations between Molecular Structure and Separations Performance

Abraham Lenhoff (University of Delaware)

#383) A Review of Platform Process Strategies: Evolution, Opportunities & Pitfalls

Brian Kelley (Genentech, Inc.)

#406) Abandoning Geometric Rules – the Evolution of

Nigel Titchener-Hooker (University College London)

WORKSHOP SESSION ABSTRACTS

What Does Industry Need from Academia?

Session Chairs:
Rainer Hahn, University of Natural Resources, Austria Andrew Zydney, The Pennsylvania State University, United States

#381) Genentech Purification Technology Development Collaborations with Suppliers and Academia

Nuno Fontes (Genentech, Inc.) Chris Dowd (Genentech, Inc.) Philip Lester (Genentech, Inc.)

#339) Meeting Industry's Needs: BTEC's Approach to Workforce Development for Influenza Vaccine Manufacturing

Gary Gilleskie (North Carolina State University) Ruben Carbonell (North Carolina State University) Jennifer Ruiz (North Carolina State University)

#364) The Future of Industry-Academic Collaborations

David Beattie (Millipore) Michael Phillips (Millipore) Gabriel Tkacik (Millipore)

Challenges of Scaling Up and Scaling Down – Expecting the Unexpected

Session Chairs:
Erik Fouts, Biomarin Pharmaceutical, Inc., United States Mike Hoare, University College London, United Kingdom

#397) Technology Transfer and Scale up of Late Stage Purification Processes

Gabriele Plewnia (Novartis Pharma SAS)

#111) A DOE Approach to Address Scale-up Issues During a Column Purification Process – A Case Study

Vish Koppaka (Biomarin Pharmaceutical, Inc.) Kris Antonsen (Biomarin Pharmaceutical, Inc.) Jun Miao (Biomarin Pharmaceutical, Inc.) Yunzhi Xiao (Biomarin Pharmaceutical, Inc.) Yanhong Zhang (Biomarin Pharmaceutical, Inc.)

High-Impact/High-Value PAT

Session Chairs:
Anurag Rathore, Indian Institute of Technology Delhi, India Kurt Brorson, Food and Drug Administration, United States

#204) Remarks on High Value/ High Impact PAT in Bioprocessing

Kurt Brorson (Food and Drug Administration)

#214) Performance of On-Line HPLC-Based PAT for Real-Time Chromatography Pooling during Large Scale Manufacturing

Oliver Kaltenbrunner (Amgen) Yuefeng Lu (Amgen)
Ken Lawson (Amgen)

Raw Material Impact on Process Performance and Sustainability

Session Chairs:
David Robbins, MedImmune, Inc., United States Richard Siegel, Janssen R&D LLC, United States

#400) The Impact of Silent Resin Variations on Downstream Process Performance

Gerlind Stoller (Sandoz GmbH)

#330) Securing the Raw Materials Supply Chain, a Vendor Perspective

John Daicic (GE Healthcare) David Raw (GE Healthcare)

#166) Evolution of Platform Resins: Collective Experiences with a Mixed- mode Anion Exchange Resin and Proactive Management of Future Generation Resins

Mark Teeters (Janssen R&D,LLC), Pedro Alfonso (Janssen R&D,LLC) Terry Benner (Janssen R&D, LLC) Mike Capaldi (Janssen R&D, LLC) John Knighton (Janssen R&D,LCC) Allen Magill (Janssen R&D, LLC)

POSTER SESSION ABSTRACTS

Session Chairs:
Steve Cramer, Rensselaer Polytechnic Institute, United States Charles Haynes, University of British Columbia, Canada
Brian Kelley, Genentech, Inc., United States

#71) Spatial Homogeneity Analysis of Preparative Chromatoghraphy in Micro-Columns

Eric von Lieres (Research Center Jülich) Andreas Püttmann (Research Center Jülich) Birgit Stute (Research Center Jülich)

#89) Structure-Based Design of Purification Process for a New rFVIII Product

Haleh Ahmadian (Novo Nordisk A/S) Camilla Kornbeck (Novo Nordisk A/S)

#90) Use of Dextran Sulfate to Minimize Precipitation During Protein A Affinity Chromatography

Mi Jin (Bristol-Myers Squibb Company) Sanchayita Ghose (Bristol-Myers Squibb Company) Shih-hsie Pan (Bristol-Myers Squibb Company) Siegfried Rieble (Bristol-Myers Squibb Company) Cherie Strain (Bristol-Myers Squibb Company) Jennifer Zhang (Bristol-Myers Squibb Company)

#100) Technology Screening for Robust Development of Primary Recovery Strategies for High Cell Density Mammalian Cell Cultures

Daria Popova (University College London) Suzanne Farid (University College London) David Pain (Lonza Biologics) Nigel Titchener-Hooker (University College London)

#104) Polishing by Negative Mode Chromatography: A Step Further in Virus Particles Purification

Cristina Peixoto (IBET)
Patrik Adielsson (GE Healthcare Bio-Sciences AB, Uppsala Sweden) Anna Åkerblom (GE Healthcare Bio-Sciences AB, Uppsala Sweden) Paula M. Alves (IBET/ITQB-UNL)
Manuel J.T. Carrondo (IBET/ITQB-UNL/FCT-UNL)
Tobias Söderman (GE Healthcare Bio-Sciences AB, Uppsala Sweden) Tiago Vicente (IBET/ITQB current address: Red Biotech)

#113) New Synthetic Depth Filter Material to Address Desired Product Clarity and Purity

Nathalie Fraud (Sartorius Stedim Biotech)
Natarajan Ramasubramanyan (Abbott Bioresearch Center) Linda Rich (Abbott Bioresearch Center)
Rene Faber (Sartorius Stedim Biotech) Axel Thiefes (Sartorius Stedim Biotech)

#115) PDADMAC Flocculation of CHO Cells with Non-ionic Polymers and Surfactants

Thomas McNerney (Amgen) Jeanine Bussiere (Amgen) Juliane Carvalho (Amgen) Monica Goss (Amgen) Matthew Hammond (Amgen) Krista Petty (Amgen) Rob Piper (Amgen) Anne Thomas (Amgen) Xiaoyang Zhao (Amgen)

#126) PEGylation, Detection and Chromatographic Purification of Site- specific PEGylated CD133 in Route to Stem Cell Separation

Marco Rito-Palomares (ITESM Biotechnology Center) Mirna Gonzalez-Gonzalez (ITESM Biotechnology Center) Karla Mayolo-Deloisa (ITESM Biotechnology Center)

#138) Comparison of Antibody Stability under Thermal and Interfacial Shear Stress for IgG1 and IgG4 Subtypes

Daniel Bracewell (University College London) Roumteen Tavakoli-Keshe (University College London) Olatomirin Kolade (University College London)
Richard Turner (MedImmune)

#140) Making Depth Filtration More Attractive for Disposable Harvesting of Mammalian Cell Culture

John Pieracci (Biogen Idec) James Chrostowski (Biogen Idec) Greg Evangelist (Biogen Idec) Jonathan Romero (Biogen Idec)

#142) Post-translational Modification Profile of Complex Recombinant Proteins: Control, Variability and Interaction of Process and Product Quality Attributes

Kevin Peeters (Genzyme Flanders)

#146) Viral Clearance and mAb Capture by Cation Exchange Chromatography, as an Alternative to Protein A

Kurt Brorson (Food and Drug Administration)

#174) Isolation and Characterization of Aggregates of a Bispecific CrossMab

Thomas von Hirschheydt (Roche Diagnostics GmbH)

#190) The Use of Temperature Dependent Intrinsic Fluorescence for the Analysis of the In-process Stability of a Protein

John Welsh (Pall (Europe) Ltd.) Staphanie Hyde (Pall (Europe) Ltd.) John Woodgate (Pall (Europe) Ltd.)

#198) High-yield Scalable Downstream Processing of a Virus-like Particle Vaccine against Group A Streptococcus

Yap Pang Chuan (The University of Queensland) Mervyn Liew (The University of Queensland) Anton Middelberg (The University of Queensland)

#199) The Intensified Bioprocessing of Biosurfactants

Anton Middelberg (University of Queensland) Michael Brech (University of Queensland)
Mirjana Dimitrijev-Dwyer (University of Queensland)

#201) Predictive Scaledown Model of Antibody Disulfide Bond Reduction during Anoxic Hold and Its Implementation during Candidate Selection

Hanne Bak (Regeneron Pharmaceuticals)

#206) Unexpected Performance of a Validated Chromatography Step

David Kahn (Human Genome Sciences, Inc.)

#210) Cation Exchange Chromatography in mAb Purification: In-depth Understanding of Resin Characteristics that Affect Monomer/Aggregate Separation

Arthur Hewig (Amgen)
Matthias Jöhnck (EMD Millipore) Anna Senczuk (Amgen)
Sigrid Sturmfels (EMD Millipore) Yinges Yigzaw (Amgen) Dominic Zorn (EMD Millipore)

#218) Modelling Reversed-Phase Chromatography

Martin Breil (Novo Nordisk A/S) Jorgen Mollerup (PrepChrom)
Soren Sondergaard Frederiksen (Novo Nordisk A/S)

#223) Single-column Continuous Chromatography

Matthias Franzreb (Karlsruhe Institute of Technology) Tobias Müller (Karlsruhe Institute of Technology) Owen R.T. Thomas (University of Birmingham UK)

#226) Towards the Development of Platform Purification Processes for Domain Antibodies Expressed in E.coli

David Paolella (GlaxoSmithKline) Andre Dumetz (GlaxoSmithKline) Kent Goklen (GlaxoSmithKline) Kathryn Jones (GlaxoSmithKline) Jeff Kurdyla (GlaxoSmithKline) Jessica Lewis (GlaxoSmithKline) Antonio Ubiera (GlaxoSmithKline)

#228) Lessons Learned from the Purification of Plasma Proteins

Karl McCann (CSL Biotherapies) Joseph Bertolini (CSL Biotherapies) Todd Nikolof (CSL Biotherapies) Gerard Seneviratne (CSL Biotherapies) John Wu (CSL Biotherapies)

#251) The Key to Quality by the Design in DSP: Computer Aided Design

Joergen M. Mollerup (PrepChrom) Martin P. Breil (Novo Nordisk A/S)
Søren Søndergaard Frederiksen (Novo Nordisk A/S)

#260) Characterization of Interaction Mechanisms on Mixed-mode Chromatography Sorbent: From Separation Optimization to CHOPs Identification for Better Exploitation in Mab Purification Processes

Rene Gantier (Pall Life Sciences) Charlotte Cabanne (ENSTB Bordeaux) Jerome Pezzini (ENSTB Bordeaux) Xavier Santarelli (ENSTB Bordeaux) Magali Toueille (Pall Life Sciences)

#261) Diafiltration Approach for Single-pass TFF Processing

Jon Petrone (Pall Life Sciences) Engin Ayturk (Pall Life Sciences) Jennifer Griffin (Pall Life Sciences) Kirsten Jones (Pall Life Sciences)

#265) In Silico QbD Applied to a Continuous Chromatography Process

Marc Bisschops (Tarpon Biosystems) Mark Brower (Merck & Co., Inc.)
Danielle Horneman (Batavia Bioservices B.V.)

#266) Physical Characterization of Protein-Ligand Interaction by Acoustic Wave Impedance

Guilherme Ferreira (University of Algarve) Jorge de-Carvalho (University of Algarve) Rogério Rodrigues (University of Algarve) Luís Rosa (University of Algarve)

Brigitte Tomé (University of Algarve)

#268) Preventing Protein Aggregation by Naturally Occurring and Designed Osmolytes

Hans Kiefer (Biberach University of Applied Sciences) Maike Eisenkolb (Biberach University of Applied Sciences) Yuguo Zang (Biberach University of Applied Sciences)

#274) Novel Soluble mRNA-display Combinatorial Libraries of Cyclic Peptides: Synthesis and Application to the Identification of Ligands that Bind to the Fc Fragment of hIgG

Ruben Carbonell (North Carolina State University) Mahmud Hussain (North Carolina State University) Stefano Menegatti (North Carolina State University) Amith Naik (North Carolina State University)
Balaji Rao (North Carolina State University)

#275) Model-Assisted Risk Analysis for Coupled Process Steps

Karin Westerberg (Lund University)
Ernst Broberg Hansen (Novo Nordisk A/S) Bernt Nilsson (Lund University)
Lars Sejergaard (Novo Nordisk A/S)

#276) Case Study: Novel Approach of Coupling Parvovirus Filtration to a Chromatography Step for Facility Fit

Debola Banerjee (Genentech, Inc.) John Lazzareschi (Genentech, Inc.) Polly Mak (Genentech, Inc.)
Kevin Shomglin (Genentech, Inc.) Rob van Reis (Genentech, Inc.)

#277) Characterization of Particle Removal during the Harvest Process

Sheldon Oppenheim (Millenium Pharmaceuticals, Inc.) Kevin Carrigan (Millenium Pharmaceuticals, Inc.)

#282) Purification and Production of Protein Conjugates Using Membrane Systems

Andrew Zydney (The Pennsylvania State University)

#283) How has (R)evolution in Downstream Processing Impacted Virus Clearance?

Adith Venkiteshwaran (Eli Lilly and Company) Dayue Chen (Eli Lilly and Company)
Daniel Strauss (Eli Lilly and Company) Victor Vinci (Eli Lilly and Company)

#287) Investigations into High-titre Capture-Chromatography Challenges

Ann-Marie de Villiers (Crucell Holland BV) Marcel de Vocht (Crucell Holland BV) Charles Hensgens (Crucell Holland BV)
Tarit Mukhopadhyay (University College London) Nigel Titchener-

Hooker (University College London)

#293) Opportunities and Challenges for Nanofiber Membrane Adsorption Systems: Case Studies and Dynamic Adsorption Breakthrough Modeling

Todd Menkhaus (South Dakota School of Mines and Technology) Kelsey Feige (South Dakota School of Mines and Technology) Hao Fong (South Dakota School of Mines and Technology) Barbara Hadrava (South Dakota School of Mines and Technology)
Steven Schneiderman (South Dakota School of Mines and Technology) Lifeng Zhang (South Dakota School of Mines and Technology)

#295) Ultrafiltration of High Concentration Proteins

Herbert Lutz (EMD Millipore)

#297) Integration of Molecular Dynamics and Experiments to Design Mimetic Affinity Membranes

Cristiana Boi (University of Bologna) Simone Dimartino (University of Bologna) Giulio Sarti (University of Bologna)

#300) A New Disposable Technology for Chromatographic Purification of Biopharmaceuticals

David Yavorsky (Merck Millipore) John Amara (Merck Millipore) Benjamin Cacace (Merck Millipore)

#302) Implementation of a Fully-integrated QbD Approach for a MAb Process: From CQAs to CPPs to Control System

Tony Cano (Genentech, Inc.)

#304) Seeing Single Proteins Moving, Binding, and Competing in Chromatographic Adsorbents

Richard Willson (University of Houston) Wen-hsiang Chen (University of Houston) Charlisa Daniels (Rice University)
Indhu Kanakaraj (University of Houston) Lydia Kisley (Rice University)
Katerina Kourentzi (University of Houston) Christy Landes (Rice University)
Nitesh Poddar (Rice University) Nick Taylor (Rice University)

#305) Enhancing Selectivity in Affinity Chromatography via PEGylated Macromolecular Affinity Ligands or How to Make Protein A Media More Expensive

Todd Przybycien (Carnegie Mellon University) Jorge Benevides (Tecnologico de Monterrey)
Jose Gonzalez-Valdez (Tecnologico de Monterrey) Marco Rito-Palomares (Tecnologico de Monterrey) Alex Yoshikawa (Carnegie Mellon University)

#319) Challenges in Purification of Fusion-Protein Therapeutics

Michiel Ultee (Laureate Biopharmaceutical Services)

#322) Modeling of Protein Aggregation in Preparative Chromatography

Bernt Nilsson (Lund University)
Ernst Broberg Hansen (Novo Nordisk A/S) Thomas Budde Hansen (Novo Nordisk A/S) Marcus Degerman (Lund University)
Frida Ojala (Lund University) Arne Staby (Novo Nordisk A/S)

#327) Protein Crystallization – From Phase Diagrams to Process

Jürgen Hubbuch (Karlsruhe Institute of Technology) Stefanie Alten (Karlsruhe Institute of Technology) Bianca Cornehl (Karlsruhe Institute of Technology) Sybille Ebert (Rentschler Biotechnologie) Hans Kiefer (Biberach University of Applied Sciences) Matthias Kind (Karlsruhe Institute of Technology) Hermann Nirschl (Karlsruhe Institute of Technology)
Franz Nothelfer (Boehringer Ingelheim Pharma GmbH & Co. KG) Natalie Schnabel (Karlsruhe Institute of Technology)
Yuguo Zang (Biberach University of Applied Sciences)

#331) Recombinant PEGylated Antibody Fragments: Product-related Species Profiling, Monitoring and Elimination during Manufacture of Antibody-based Therapeutics

Mariangela Spitali (UCB S.A.) Stefanos Grammatikos (UCB S.A.) Mark Pearce-Higgins (UCB S.A.) Smita Thobhani (UCB S.A.)

#332) Integration of Biotransformation and SMB Separation for the High- yield Production of Fine Chemicals

Matthias Bechtold (ETH Zurich)
Andreas Bosshart (ETH Zurich) Sven Panke (ETH Zurich)
Nina Wagner (ETH Zurich)

334) Predicting the Separation Performance of Electrostatic Interaction Chromatography of Proteins and Other Biological Products When Mobile Phase Properties Are Tuned

Shuichi Yamamoto (Yamaguchi University) Yu Isakari (Yamaguchi University)
Daisuke Itoh (Yamaguchi University) Ryo Maeda (Yamaguchi University)
Noriko Yoshimoto (Yamaguchi University)

#335) Scalable Embryonic Stem Cell Purification Using a Laser Direct-write 3D Microfluidic Device

Craig J Williams (Heriot Watt University) Debaditya Choudhury, (Heriot Watt University) P de Sousa (University of Edinburgh)

A Kar (University of Edinburgh)
L Paterson (Heriot Watt University) S Pells
(University of Edinburgh)
Will Ramsay (Heriot Watt University) Nik
Willoughby (Heriot Watt University)

#340) Viral Vaccine Purification and Inactivation Challenges

Etienne Boutry (Sanofi Pasteur Inc)

#341) Antibody Drug Conjugates: A New Platform of Protein Therapeutic Molecules

Michel Eppink (Synthon) Patrick
Beusker (Synthon) Vincent de
Groot (Synthon) Guy de Roo
(Synthon) Bram Kamps (Synthon)

#347) Efficient Removal of Endotoxins from Biopharmaceutical Preparations

Dev Baines (Prometic Biosciences Ltd) Steve Burton
(Prometic Biosciences Ltd) Sharon Williams (Prometic
Biosciences Ltd)

#349) Novel Hollow Fiber Membrane Adsorber, QyuSpeed™ D, Expands the Options Available in the Purification Tool Box

Tomoyuki Miyabayashi (Asahi Kasei Bioprocess, Inc.) Michael Rabin
(Asahi Kasei Bioprocess, Inc.)
Chie Sudo (Asahi Kasei Medical Co., Ltd, Bioprocess division) John Fisher
(Asahi Kasei Bioprocess, Inc.)
Hironobu Shirataki (Asahi Kasei Medical Co., Ltd, Bioprocess division)

#353) Rapid Screening of Mixed-Mode Chromatography Resins for Monoclonal Antibody Polishing Purification

Chen Wang (Abbott Bioresearch Center)
Shilpa Ananthakrishan (Abbott Bioresearch Center) Johanna
Gervais (Abbott Bioresearch Center)

#363) Membrane Technology Challenges for Bioprocessing

Georges Belfort (Rensselaer Polytechnic Institute)

#365) Control Strategy for Fine Purification: Ceramic Hydroxyapatite Case Study

George Parks (Millenium Pharmaceuticals, Inc.) Paul Hanson
(Millenium Pharmaceuticals, Inc.)
Sheldon Oppenheim (Millenium Pharmaceuticals, Inc.)

#366) A New Method to Fabricate Membranes by Glassy Self Assembly Templating

Chia-Chi Ho (University of Cincinnati) Ross Andrews
(University of Cincinnati) Carlos Co (University of
Cincinnati) Hitesh Dave (University of Cincinnati)
Feng Gao (University of Cincinnati)

#371) Achieving High Mass-Throughput of Therapeutic Proteins Through Parvovirus Retentive Filters

Daniel LaCasse (Pfizer, Inc.) Jonida Basha (Pfizer, Inc.) Glen Bolton (Biogen Idec)

#372) Rapid Development of an Early Phase Process and Minimization of Charge Variability

Michael Murray (Fujifilm Diosynth Biotechnologies) Greg Adams (Fujifilm Diosynth Biotechnologies) Rae Chavez (Fujifilm Diosynth Biotechnologies) Leisha Collins (Fujifilm Diosynth Biotechnologies) Lindsey Denning (Fujifilm Diosynth Biotechnologies) Valeri Fayer (Fujifilm Diosynth Biotechnologies) Keith Kulowiec (Fujifilm Diosynth Biotechnologies) Philip Ropp (Fujifilm Diosynth Biotechnologies) Matthew Smith (Fujifilm Diosynth Biotechnologies) Gayathri Vasudevan (Fujifilm Diosynth Biotechnologies) Linda Yi (Fujifilm Diosynth Biotechnologies)

#377) Imparting Beaded Chromatography Matrices with Multiple Layers and Functions

Owen R.T. Thomas (University of Birmingham UK) Kritsadanchalee Karnchanasri (University of Birmingham UK) Eirini Theodosiou (Loughborough University UK) James Walsh (University of Liverpool) Thomas Willett (University of Birmingham UK)

#382) Developing an Appropriate Design Space Strategy to Mitigate Variability in Downstream Processing Operations

Lynn Conley (Biogen Idec)

#385) Applying Chemometrics to Chromatography Data

Adeyma Arroyo (Genentech, Inc.) Christopher Bork (Genentech, Inc.) Michael Milligan (Genentech, Inc.) Victor Saucedo (Genentech, Inc.) Mark Smith (Genentech, Inc.)

#389) Tailor-made Bioseparation Resins Manufactured by Engineered Bacteria

Bernd Rehm (Polybatics Ltd)

#391) Understanding Solubility through Design Space Approach

David Nichols (Shire Human Genetic Therapies) Yiming Yang (Shire Human Genetic Therapies)

#395) High Pressure Refolding: A cGMP Scaled Technology for Improved Industrial Refolding, Increasing Throughput with Decreased Material and Energy Costs

Matthew Seefeldt (Barofold Inc)

#396) A Capacitance Immunobiosensor for Quality Control of Protein Preparations

Bo Mattiasson (University of Lund)

Martin Hedström (CapSenze HB)

#402) Critical Parameter for Continuous Inclusion Body Preparation

Norbert Palma (Sandoz AG) Martin Ludwiczek (Sandoz AG)

#420) Purification of Biopharmaceuticals Using a Countercurrent 2-Column Chromatography Process (MCSGP)

Massimo Morbidelli (ETH Zurich) Thomas Müller-Späth (ETH Zurich) Guido Ströhlein (ETH Zurich) Lars Aumann (ETH Zurich) Michael Bavand (ETH Zurich)