WORKSHOP 1 - Preparative Chromatography for Biopharmaceuticals
9:00am - 12:30pm

Focus: Biomolecule chromatography, stationary phases, binding capacity and selectivity, mass transfer, modeling, design for capture and step elution

This workshop will focus on the theory and practice of biomolecule chromatography. Since mass transfer and the structure of the stationary phase influence deeply chromatographic performance, the main emphasis is on describing adsorption/desorption kinetics in single and multicomponent systems and determining the relationship between stationary phase properties and process performance. The latest advances in stationary phase developments will be reviewed along with methods for their experimental characterization. Design and optimization strategies for capture and high-resolution applications will be discussed.

Topics: Adsorption equilibrium and transport in single and multicomponent systems; Stationary phases for small and large biomolecules; Design and optimization for capture and high-resolution steps

Lecturers:

Giorgio Carta received his Ph.D. in Chemical Engineering from the University of Delaware in 1984. Since then he has been a professor in the Department of Chemical Engineering at the University of Virginia, where his research focuses on transport phenomena and bioseparations. He regularly organizes professional courses on various aspects of bioseparations, including a course on protein chromatography development and scale-up together with Alois Jungbauer.

Alan Hunter received his Ph.D. in Chemical Engineering from the University of Virginia in 2002 and is currently Principal Scientist in the Process Biochemistry Group at MedImmune. Prior to joining MedImmune he held positions of Process Engineer at Cambrex Bio Science Baltimore, and of Senior Principal Scientist at Pfizer Biologics. Dr. Hunter has broad biotechnology experience and expertise in areas including process development for large-scale cGMP manufacture of biologics, recombinant biopharmaceutical purification, and technology transfer and scale-up.

Alois Jungbauer is the head of protein technology and downstream processing at the Department of Biotechnology of the University of Natural Resources and Applied Life Sciences in Vienna (Austria). For more than 20 years, Professor Jungbauer has worked in biochemical engineering, with a focus on bioseparation, where he has published widely and holds 15 patents. For over 10 years, he has organized a biennial professional course in protein chromatography focused on mass transfer, dispersion, and scale-up.
EDUCATIONAL TRAINING WORKSHOP PROGRAM
– Must pre-register to attend workshops –

WORKSHOP 2 – Preparative Chromatography for Intermediates and APIs
9:00am - 12:30pm

**Focus:** Small molecules, HPLC, column packing, gradient elution, overloaded chromatography, SFC, SMB, examples and industrial applications

This workshop will focus on development of method for the preparative purification of small molecules for the pharmaceutical industry. After an introduction of the theory, optimization and practice of prep HPLC, SMB and SFC for small molecule separations, the instructors will present practical approaches to the development of preparative separation through a series of examples. The attendees will learn valuable information and techniques to apply in the laboratory and at manufacturing scale to increase throughput and performance.

**Topics:** Prep HPLC batch - Theory, optimization and practice; SMB - Principle and technology; SMB - Examples and applications; SFC - Theory, equipment and examples

**Lecturer:**

Olivier Dapremont has worked on the development of SMB technology since 1992. He is Director of Process Technologies at AMPAC Fine Chemicals where his role encompasses the development of SMB separations using multiple SMB units ranging from 4.6 mm to 1 m in diameter as well as developing continuous processes for the manufacturing of APIs.
EDUCATIONAL TRAINING WORKSHOP PROGRAM
– Must pre-register to attend workshops –

WORKSHOP 3 - Multi-Column Continuous Chromatography for Downstream Purification of Biomolecules
1:30pm - 4:30pm

Focus: Focus on continuous chromatography for biomolecules, isotherms for biomolecules, SMB basic principles, difference between SMB for small molecules and SMB for biomolecules, challenges, practical examples.

Chromatographic processes are essential for the downstream purification of bio-molecules. During the last 10 years, a tremendous increase in the upstream expression levels, especially for monoclonal antibodies requires a significant shift in the downstream approach. To overcome “bottlenecks”, the implementation of Multi-Column Continuous Chromatography (Bio-MCC) became of interest. Therefore, the workshop will introduce the audience to the fundamentals on Bio-MCC and provide guidelines for the process and equipment design after reviewing the downstream chromatographic processes and the Simulated Moving Bed (SMB) technology. The workshop will present applications and current developments. Although, the SMB technology has a proven record to bring synthetic pharmaceuticals faster to the market and to purify non-pharmaceutical bio-molecules at a large industrial scale; barriers still remain to implement the technology into the bio-pharmaceutical industry. These barriers will be identified and ways how to eliminate them. In particular, eliminating barriers related to column and equipment hardware, packing material, solvent systems, CIP of the systems, bio-molecule characteristics and regulatory constraints to allow continuous chromatographic processes to become part of the processing platform in the bio-pharmaceutical industry. This workshop is a complement to the basics of prep chromatography presented in the morning.

Topics: Simulated Moving Bed and Multicolumn Continuous Chromatography technology for biomolecules, fundamentals and design criteria, challenges and opportunities, regulatory constraints

Lecturer:

Kathleen Mihlbachler has worked in the field of separation technology with an emphasis on process chromatography for more than 15 years. As a Sr. Researcher at BMS, Eli Lilly and Pfizer, she worked on the development, scale-up and manufacturing of purification/separation processes for chiral and non-chiral compounds, peptides and proteins, in particular to implement continuous processes. Since the fall of 2011, Dr. Mihlbachler has taught in the Department of Chemical, Biological and Pharmaceutical Engineering at New Jersey Institute of Technology. She is also an Independent Consultant in the area of preparative chromatography and related separation technologies.
EDUCATIONAL TRAINING WORKSHOP PROGRAM
– Must pre-register to attend workshops –

WORKSHOP 4 - Regulatory and Marketing Fundamentals and QbD Tools to Bring Biomolecules to Market and Keep Them There
1:30pm - 4:30pm

Focus: This workshop will focus on Quality by Design, Quality Systems Management, Science-based Risk Management, Process Analytical Technology and Continuous Process Improvement as tools that can be incorporated into basic drug development processes. We will examine the relationship between good drug development science, quality and regulatory flexibility, with emphasis on application to the biopharmaceutical industry. Particular attention will be placed on the practice of Quality by Design. A practical study of how the integration of quality and risk management is used in an application to bring a mAb to market will be presented. In addition, we will address the challenges for technology and regulation created by the emerging biosimilars industry along with the current status of internationally developed guidance.

Topics: Regulatory aspects, QbD, Process Analytical Technology, Quality System Management, Biosimilars, Marketing

Lecturers:

After a multi-decade career with the U.S. Food and Drug Administration, in 2009 Lois Ann Beaver founded a regulatory consulting group, LAB Enterprises. While working in FDA’s Office of the Commissioner, Lois served on the FDA Pharmaceutical Quality Council that conceived and developed quality by design; led activity for FDA’s joining the international Pharmaceutical Inspection Cooperation Scheme; worked as liaison with international organizations such as WHO, most recently focusing on biosimilars; managed the export program for international investigations of unapproved pharmaceuticals; was associate director for international harmonization working on international best practice and standardization activities such as the ICH; was US Coordinator for Veterinary ICH; and served as delegate to the APEC (Asia Pacific Economic Cooperation) Life Sciences Innovation Forum. Lois also led international projects on anti-counterfeiting of medical products and good manufacturing practices in pharmaceutical firms in emerging countries, and established a pharmaceutical information center in Cairo.

Gisela Ferreira received her Ph.D. in Chemical Engineering from the University of Maryland Baltimore County in 2001 and is currently Senior Scientist in the Process Biochemistry Group at MedImmune. Prior to joining MedImmune she held positions as Senior Scientist at Medarex in the downstream department. Dr. Ferreira has broad biotechnology experience and expertise in areas including process development for large-scale cGMP manufacture of biologics, recombinant biopharmaceutical purification (early and late stage development), QbD, technology transfer and scale-up.
The Sunday Training Workshop program is designed to provide advanced tutorials covering various aspects of process chromatography. The Workshops are presented by leading academic and industrial scientists and engineers and cover both fundamentals as well as real-world application examples. Click here for details describing the workshops.

9:00 AM - 12:30 PM  
Workshop 1: Preparative Chromatography for Biomolecule Purification  
Burroughs Room  
Click here to register to attend

9:00 AM - 12:30 PM  
Workshop 2: Preparative Chromatography for Intermediates and APIs  
Lewis Room  
Click here to register to attend

1:30 - 4:30 PM  
Workshop 3: Multi-Column Continuous Chromatography for Downstream Purification of Biomolecules  
Burroughs Room  
Click here to register to attend

1:30 - 4:30 PM  
Workshop 4: Regulatory and Marketing Fundamentals and QbD Tools to Bring Biomolecules to Market and Keep Them There  
Lewis Room  
Click here to register to attend

6:00 - 7:30 PM  
SYMPOSIUM REGISTRATION OPEN

6:00 - 7:30 PM  
WELCOME RECEPTION & EXHIBITION

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### Monday, July 21, 2014

7:30 AM  
Symposium Registration Open

10:10 AM - 5:10 PM  
Exhibition Open

8:20 AM  
Welcome and Opening Remarks

1. Monday Keynote: Industrial Case Studies in Protein Chromatography  
   Session Chair: Giorgio Carta, University of Virginia, Charlottesville, VA, USA

8:30 AM  
Custom Affinity Chromatography Development for Novel Molecule Purification.  
Alan Hunter1, Xiangyang Wang1, Timothy Pabst1, Michaela Wendeler1, Pim Hermans2,  
1MedImmune, Gaithersburg, MD, USA; 2Life Technologies, Leiden, NETHERLANDS

8:50 AM  
Leveraging High Throughput Screening Techniques to Expedite Alternative Capture Resins Selection for Bi-ScFv Purification. Balakumar Thangaraj, Kenneth Prentice, Jason O'Neill, Ronald Gillespie, Amgen, Seattle, WA, USA

9:10 AM  
Towards a Protein A Free Monoclonal Antibody Purification Platform: Case Studies in Membrane Chromatography. Ying Hou, Mark Brower, David Pollard, Merck & Co. Inc., Kenilworth, NJ, USA

9:30 AM  
Enabling High Mass Recovery in Downstream Purification of a High Titer Monoclonal Antibody: Beyond Flow-through. James Patch, Marc Wong, Evelyn Martin, Mark Iverson, Deepa Nadarajah, Genentech, South San Francisco, CA, USA
9:50 AM Investigating the Mechanisms of a Protein A Resin Fouling for Improved Lifetime Performance. William Daniels¹, Shaojie Zhang², Giorgio Carta², Corey Allan³, Jeffrey Salm¹, Judy Glynn⁵, Joseph Martin⁵, Christopher Gallo¹, Ranga Godavarti¹, ¹Pfizer, Andover, MA, USA; ²UVA, Charlottesville, VA, USA; ³Pfizer, St Louis, MO, USA

10:10–10:40 AM Break

2. Monday Session: Molecular and Process Modeling

10:40 AM Biophysical Insights into the Molecular and Thermodynamic Basis of Protein Selectivity in Multimodal Chromatography. Kartik Srinivasan, Maria M. Lopez, Scott A. McCallum, Blanca Barquera, Steven M. Cramer, Rensselaer Polytechnic Institute, Troy, NY, USA

11:00 AM Conformational Change of Proteins upon Adsorption onto Nanoparticles: Effect of Surface Curvature. Peter Satzer¹, Frantisek Svec², Alois Jungbauer¹, ¹University of Natural Resources and Life Sciences, Vienna, AUSTRIA; ²The Molecular Foundry E.O. Lawrence Berkeley National Laboratory, Berkeley, CA, USA

11:20 AM Protein Elution within Polysaccharidic Stationary Phases for Ion-exchange. James Angelo, Abraham Lenhoff, University of Delaware, Newark, DE, USA

11:40 AM Study on Kinetics of Protein Refolding in Different Chromatographic and Non-chromatographic Systems. Sylwia Rys, Renata Muca, Wojciech Piatkowski, Dorota Antos, Rzeszow University of Technology, Rzeszow, POLAND

12:00 PM Adsorption Model onto RPLC-C18 Stationary Phases Doped with Positively Charged Surface Ligands: Potential Application for Bio-Purification. Fabrice Gritti¹, Uwe Neue², Pamela Iraneta², Georges Guiochon¹, ¹University of Tennessee, Knoxville, TN, USA; ²Waters Corporation, Milford, MA, USA

12:20-1:50 PM PAUSE, EXHIBITS, POSTERS, FREE VENDOR WORKSHOPS

1:50–3:20 PM POSTER SESSION I

3A. Monday Parallel Session: Purification Strategies and Processes for Biomolecules

3:20 PM Solvent Codulated IEC on the Next Level: Solubility Enhancers Give Access to Higher Resolution and Protein Concentration. Simon Kluters¹, Theresa Hiller¹, Thomas von Hirschheydt², Christian Frech¹, ¹University of Applied Sciences, Mannheim, GERMANY; ²Roche Diagnostics GmbH, Penzberg, GERMANY

3:40 PM TBA

4:00 PM Development of a Downstream Process for Purification of Interferon α-2a. Jamil Shanagar, Kjell Eriksson, Charlotte Brink, Sara Grönlund, Ola Lind, Anna Moberg, Ewa Pol, Maria Winkvist, Veronica Fridh, GE Healthcare Bio-Sciences AB, Uppsala, SWEDEN

4:20 PM Particle Movement in Expanded Beds under the Spotlight. Stephanie Ewert¹, Joseph Gargiuli¹, David Parker¹, Serafim Bakalis¹, Eirini Theodosiou², Owen Thomas¹, ¹University of Birmingham, Birmingham, UK; ²Loughborough University, Loughborough, UK

4:40-5:10 PM Break
3B. Monday Parallel Session: Stationary Phases I

3:20 PM  A New Agarose Based Platform for Protein Purification. Hans Johansson¹, Alessandra Bassò², Patrick Gilbert³, Mark Hicks³, Purolite, Uppsala, SWEDEN; Purolite, Llantrisant, UK; Purolite

3:40 PM  Characterization of a Newly Developed High Capacity Alkaline Resistant Recombinant Protein A Resin. Atis Chakrabarti¹, Kevin O'Donnell³, K Nakamura², S Nakatani², Tosoh Bioscience LLC, King of Prussia, PA, USA; Tosoh Corporation, JAPAN

4:00 PM  Evaluation of a Novel Methacrylate Based Protein A Resin for the Purification of Immunoglobulins and Fc-Fusion Proteins. Tyler McCaw¹, Edward Koepf², Lynn Conley², University of Alabama School of Medicine, Birmingham, AL, USA; Biogen Idec, Research Triangle Park, NC, USA

4:20 PM  Using Selectivity and Resolution in the Purification of Diverse Biotherapeutics. Mark Snyder¹, Xuemei He¹, Jidong Li², Carsten Voss³, Bio-Rad Laboratories, Hercules, CA, USA; Bio-Rad Laboratories, Shenzhen, CHINA; Bio-Rad Laboratories, Munich, GERMANY

4:40-5:10 PM  Break

4A. Monday Parallel Session: Resolution of Chiral Molecules and APIs

5:10 PM  The Influence of the Buffer on the Retention Phenomena of Mefloquine Enantiomers on Switterionic Stationary Phase. Attila Felinger¹, Wolfgang Lindner¹, Csaba Szmolnik¹, University of Pecs, Pecs, HUNGARY; University of Vienna, Vienna, AUSTRIA

5:30 PM  Advances in Method Development for Preparative Chiral Chromatography. J. T. Lee¹, Clint Amoss¹, Pilar Franco², Tiago de Campos Lourenco³, Juliana Cristina Barreiro³, Quezia Bezzerra Cass³, Chiral Technologies Inc., West Chester, PA, USA; Chiral Technologies Europe, Illkirch, FRANCE; Universidade Federal de Sao Carlos, Sao Carlos, BRAZIL


6:10 PM  Pause

4B. Monday Parallel Session: Stationary Phases II

5:10 PM  Effects of Ligand Density on Properties of Tentacular Ion-Exchange Adsorbents. Rahul Bhambre¹, Michael Phillips², Christopher Gillespie², Abraham Lenhoff¹, University of Delaware, Newark, DE, USA; EMD Millipore, Bedford, MA, USA; Merck Millipore, Darmstadt, GERMANY

5:30 PM  Bespoke Chromatography Materials for the Separation of Biological Nanoplexes. Johannes Mohr¹, Thomas Willett¹, Kritsandchalee Karnchanasri², Eirini Theodosiou², Daniel Bracewell³, Owen Thomas³, University of Birmingham, Birmingham, UK; Loughborough University, Birmingham, UK; University College London, London, UK; University of Liverpool, Liverpool, UK

5:50 PM  Ligand-assisted Chromatography for Lanthanide Separations using a Titania Sorbent. Lei Ling, Purdue University, West Lafayette, IN, USA

6:10 PM  Pause
Tuesday, July 22, 2014

5. Tuesday Keynote: Advancing Technologies in Support of Small Scale Purifications for Medicinal Chemistry, Drug Discovery and Development
Session Chairs: Larry Miller and Manuel Ventura, Amgen Inc., S. San Francisco, CA, USA

8:30 AM  Isolation of Impurities using SFC: Fast, Economical, and Enabling. Jeffrey Kiplinger, Paul Lefebvre, John Tipping, Averica Discovery Services, Marlborough, MA, USA

8:50 AM  Purification Support of Late Stage Functionalization Chemistries in Drug Discovery. Eric Streckfuss, Merck Research Laboratories, Rahway, NJ, USA

9:10 AM  Supercritical Fluid Chromatography in Open Access Purification for Medicinal Chemistry Support. David Dunstan, Joseph Twomey, Melissa Grondine, Poirier Jennifer, John Reilly, Novartis, Cambridge, MA, USA

9:30 AM  Development and use of a Dual-mode SFC/RPLC Mass-directed Purification System in Medicinal Chemistry. Kanaka Hettiarachchi, Qifeng Xue, Theravance Inc., South San Francisco, CA, USA


10:10-10:40 AM  Break

6. Tuesday Keynote: Continuous Chromatography
Session Chair: Olivier Dapremont, AMPAC Fine Chemicals, Rancho Cordova, CA, USA

10:40 AM  A Few Basic Considerations for Comparing Batch and Continuous Chromatography. Roger-Marc Nicoud, Lay Saint Christophe, FRANCE

11:00 AM  The Largest Pharma Chromatography Plant for the Production of Omega-3’s. Jean Blehaut, Eric Valery, Philippe Adam, Novasep, Pompey, FRANCE


11:40 AM  Analysis of Hybrid SMB-crystallization Process using a Binary Solvent. Balamurali Sreedhar1, Baochun Shen2, Huayu Li3, Ronald Rousseau1, Yoshiaki Kawajiri1, 1Georgia Institute of Technology, Atlanta, GA, USA; 2Kunming Medical University, Kunming, CHINA

12:00 PM  Relay Simulated Moving-Bed Chromatography: Design and Experimental Validation. Jose Mota, Requimte/CQFB & IBET, Caparica, PORTUGAL

12:20-12:25 PM  ANNOUNCEMENT

12:25-2:00 PM  PAUSE, EXHIBITS, POSTERS, FREE VENDOR WORKSHOPS

2:00–3:30 PM  POSTER SESSION II
### 7A. Tuesday Parallel Session: Modeling and Design of Chromatographic Processes

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<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Authors</th>
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<tbody>
<tr>
<td>3:30 PM</td>
<td>Predicting the Productivity of Capture Chromatography based on a Simplified Mechanistic Model.</td>
<td>Noriko Yoshimoto, Yu Isakari, Shuichi Yamamoto, Yamaguchi University, Ube, JAPAN</td>
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<td>3:50 PM</td>
<td>Scalability of Mechanistic Models for Ion Exchange Chromatography.</td>
<td>Thiemo C. Huuk¹, Tobias Hahn¹, Anna Osberghaus¹, Jan Griesbach², Stefan Hepbildikler², Jürgen Hubbuch¹, ¹Karlsruhe Institute of Technology (KIT), Karlsruhe, GERMANY; ²Roche Diagnostics GmbH, Penzberg, GERMANY</td>
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<tr>
<td>4:10 PM</td>
<td>General Design Method for Affinity Chromatography.</td>
<td>Lei Ling, Lee-wei Kao, Nien-Hwa, Linda Wang, Purdue University, West Lafayette, IN, USA</td>
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<tr>
<td>4:30 PM</td>
<td>Design and Optimization of Bypass-SMB: An Improved Operation for Reduced Purity Requirements.</td>
<td>Preetika Karnal¹, Arvind Rajendran², Tuomo Sainio³, ¹Indian Institute of Technology, Bombay, INDIA; ²University of Alberta, Edmonton, CANADA; ³Lappeenranta University of Technology, Lappeenranta, FINLAND</td>
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### 7B. Tuesday Parallel Session: Continuous Chromatography for Bioseparations

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<th>Time</th>
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<tr>
<td>3:30 PM</td>
<td>How to Overcome Challenges When Implementing Continuous Chromatography in the DSP.</td>
<td>Kathleen Mihlbachler, IPT - A member of LEWA-Nikkiso, Devens, MA, USA</td>
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<td>3:50 PM</td>
<td>Automated Process Development and Control of a Twin-column Counter-current Process (CaptureSMB) for Affinity Capture.</td>
<td>Thomas Muller-Spath, Nicole Ulmer, Lars Aumann, Guido Strohlein, Michael Bavand, ChromaCon AG, Zurich, SWITZERLAND</td>
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<tr>
<td>4:10 PM</td>
<td>Adenovirus Purification by Two-column, Open-loop, Size-exclusion, Simulated Countercurrent Chromatography.</td>
<td>Piergiuseppe Nestola¹, Ricardo Silva², Cristina Peixoto³, Paula Alves¹, Manuel Carrondo², Jose Mota³, ¹IBET, Oeiras, PORTUGAL; ²FCT-UNL, Caparica, PORTUGAL; ³IBET &amp; FCT-UNL, Oeiras, PORTUGAL; ⁴FCT-UNL &amp; IBET, Caparica, PORTUGAL</td>
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<td>4:30 PM</td>
<td>Comparison of Simulated Moving Bed Chromatography and Batch Chromatography using Affinity, Mixed Mode and Ion Exchange Chromatography and Different Biological Feedstreams.</td>
<td>Karl Rogler, Aleksandar Cvetkovic, Peter Levison, Rene Gantier, Pall Corporation, Westborough, MA, USA</td>
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4:50 PM Pause
### 8A. Tuesday Parallel Session: DOE & QbD for Bioprocess Development

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<th>Institution</th>
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<tr>
<td>5:00 PM</td>
<td><strong>A Quality by Design Approach: Systematic Optimization of Malaria Vaccine</strong></td>
<td>Purification with IMAC.</td>
<td>Jessica Paul, Arthur Dukart, Miriam Meyer, Gesine Cornelissen, HAW Hamburg, Hamburg, GERMANY</td>
<td>HAW Hamburg, Hamburg, GERMANY</td>
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<tr>
<td>5:20 PM</td>
<td><strong>Design of Experiments can Help to Optimize the Purification Processes for Plant-derived Biopharmaceutical Proteins.</strong></td>
<td>Johannes Buyel¹, Hannah Gruchow², Patrick Opdensteinen³, Rainer Fischer³, RWTH Aachen University, Aachen, GERMANY; Fraunhofer Institute for Molecular Biology and Applied Ecology, Aachen, GERMANY; RWTH Aachen University/Fraunhofer Institute for Molecular Biology and Applied Ecology, Aachen, GERMANY</td>
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<td>5:40 PM</td>
<td><strong>Application of DoE and HTS for the Selection of Prototype Cation-exchange Mixed-mode Sorbents that are Versatile.</strong></td>
<td>Mark Schofield¹, Alexander Martino¹, Magali Toueille², Audrey Uzel³, René Gantier¹, Pall, Westborough, MA, USA; Pall, Cergy, FRANCE</td>
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6:00 PM Pause

### 8B. Tuesday Parallel Session: Chromatographic Processes for Small Molecule Separations

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<th>Institution</th>
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<tr>
<td>5:00 PM</td>
<td><strong>A Simple Batch Recycling Scheme Applied to a Multi-component Metal Separation Problem. An Industrial Example of Improving Productivity in a System where Multiple Products must be Recovered.</strong></td>
<td>Magdalena Ciszewska, Paul O’Shaughnessy, Johnson Matthey, Reading, UK</td>
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<td>5:20 PM</td>
<td><strong>Modeling and Optimization based Design of Reactive Simulated Moving Bed Systems for Equilibrium-limited Reactions.</strong></td>
<td>Gaurav Agrawal¹, Jungmin Oh³, Balamurali Sreedhar³, Megan E. Donaldson³, Timothy C. Frank³, Alfred K. Schultz³, Andreas S. Bommarius¹, Yoshiaki Kawajiri³, Georgia Institute of Technology, Atlanta, GA, USA; Process Separations - Engineering Sciences Laboratory, The Dow Chemical Company, Midland, MI, USA; Core R&amp;D/Process Separations The Dow Chemical Company, Midland, MI, USA; Senior Research Scientist The Dow Chemical Company, Philadelphia, PA, USA</td>
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<td>5:40 PM</td>
<td><strong>Crude2Pure - Preparative HPLC Fractions to Pure, Dry Powder.</strong></td>
<td>Robert Buco¹, Masayuki Nishimura², Yosuke Iwata³, Tomoyuki Yamazaki³, Tsutomu Okoba³, Junichi Masuda³, Tsuyoshi Morikawa³, Takayuki Inoki³, Shimadzu Corporation, Marlborough, MA, USA; Shimadzu Corporation, Columbia, MD, USA; Shimadzu Corporation, Kyoto, JAPAN</td>
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6:00 PM Pause
Session Chair: Olivier Dapremont, AMPAC Fine Chemicals, Rancho Cordova, CA, USA
and Tividar Farkas, Phenomenex, Torrance, CA, USA

8:20 AM Peptide Purification via Ion-exchange Doped Reversed Phase Chromatography: A Combined Experimental and Modeling Approach. Gianluca Buffolino1, Rushd Khalaf2, Massimo Morbidelli2, Nicola Forrer3, 1Zeochem AG, SWITZERLAND; 2ETH Zürich, SWITZERLAND; 3SWITZERLAND

8:40 AM Safety by Design: The Advantages of Chromatography in the Production of Highly Active Small Molecules and Peptides. Ulf Altenhoner, Dominique Roberge, Conrad Roten, Lonza AG, Visp, SWITZERLAND

9:00 AM Peptide Preparatory Chromatography Scale up and Pitfalls. Brad DeHoff, Dennis Petersen, Valerie Paulsen, Lin Chen, Corden Pharma, Boulder, CO, USA

9:20 AM Multi-step Synthetic Peptide Purification using a Single Silica Based Sorbent. J. Preston, Jeff Layne, Marc Jacob, Phenomenex, Torrance, CA, USA

9:40-9:50 AM PRESENTATION OF AWARDS TO WINNERS OF THE BEST POSTER COMPETITION

9:50-10:10 AM Break

10. Wednesday Session: Monoliths and Membrane Chromatography
Session Chair: Igor Quinones-Garcia, Shire, Lexington, MA, USA

10:10 AM 3D Structure and Flow Properties of Polymer Based Monoliths. Alois Jungbauer1, Christian Jungreuthmayer2, Gerhard Sekot2, Petra Stepert3, 1ACIB/BOKU, Vienna, AUSTRIA; 2ACIB, Vienna, AUSTRIA; 3BOKU, Vienna, AUSTRIA

10:30 AM Design of Monoliths through their Mechanical Properties. Ales Podgornik1, Ales Savnik2, Janez Jancar2, Nika Lendero Krajnc2, 1University of Ljubljana, Ljubljana, SLOVENIA; 2BIA Separations doo, Ajdovscina, SLOVENIA

10:50 AM Protein Adsorption Performance and Mathematical Modeling of Ion-exchange Membrane Chromatography at Different Membrane Scales and Module Geometries. Chalore Teepakorn, Catherine Charcosset, Koffi Fiaty, University Lyon I - LAGEP, Villeurbanne, FRANCE

11:10 AM Performance and Economic Study of Next Generation Single-use Technologies. Kristina Pleitt, Paul Jorjorian, Gallus BioPharmaceuticals LLC, St. Louis, MO, USA
11. Wednesday Session: New Approaches for Biopurification

11:30 AM Protein Purification by Microparticles. Rainer Hahn\textsuperscript{1}, Alexander Trefilov\textsuperscript{2}, Moritz Imendoerffer\textsuperscript{2}, Alois Jungbauer\textsuperscript{1}, \textsuperscript{1}University of Natural Resources and Life Sciences, Vienna, AUSTRIA; \textsuperscript{2}Austrian Centre of Industrial Biotechnology, Vienna, AUSTRIA

11:50 AM Non-protein A, Non-column Purification of IgG. Hui Theng Gan\textsuperscript{1}, Rui Nian\textsuperscript{2}, Lihan Tan\textsuperscript{1}, Wei Zhang\textsuperscript{1}, Pete Gagnon\textsuperscript{1}, \textsuperscript{1}Bioprocessing Technology Institute, Singapore, SINGAPORE; \textsuperscript{2}Bioprocessig Technology Institute, Singapore, SINGAPORE

12:10 PM Design and Optimization of Countercurrent Tangential Chromatography for Monoclonal Antibody Purification. Amit Dutta\textsuperscript{1}, Oleg Shinkazh\textsuperscript{1}, Boris Napadensky\textsuperscript{1}, Travis Tran\textsuperscript{1}, Andrew Zydney\textsuperscript{2}, \textsuperscript{1}ChromaTan Corporation, State College, PA, USA; \textsuperscript{2}Penn State University, University Park, PA, USA

12:30-2:00 PM Lunch on own

12. Wednesday Session: Improving Bioprocess Chromatography

2:00 PM Hybrid Process Technology for Antibody Purification. Vijaykumar Dhadge\textsuperscript{2}, Ana Azevedo\textsuperscript{1}, Maria Raquel\textsuperscript{1}, Aires-Barros\textsuperscript{1}, Cecilia Roque\textsuperscript{2}, \textsuperscript{1}IST, Lisbon, PORTUGAL; \textsuperscript{2}FCT-UNL, Lisbon, PORTUGAL

2:20 PM How can we Streamline Influenza Virus Purification? Aleksandar Cvetkovic\textsuperscript{1}, Rene Gantier\textsuperscript{1}, Annelies Onraedt\textsuperscript{1}, \textsuperscript{1}Pall Life Science, Westborough, MA, USA; \textsuperscript{2}Pall International, Fribourg, SWITZERLAND

2:40 PM Characterization of the Product Related Impurities of an Fc Fusion Protein and Rational Design of a Robust Downstream Purification Process. Chao Huang, Xuankuo Xu, Udesh De Silva, Mi Jin, Zhengjian Li, Bristol-Myers Squibb, East Syracuse, NY, USA

3:00-3:20 PM Break

13. Wednesday Keynote: Supercritical Fluid Chromatography (SFC)

Session Chair: Georges Guiochon, University of Tennessee, Knoxville, TN, USA

3:20 PM The Modeling of Overloaded Elution Band Profiles in Supercritical Fluid Chromatography. Peter Vajda, Georges Guiochon, University of Tennessee, Knoxville, TN, USA

3:40 PM Scalability and Adsorption Behavior in Chiral Supercritical Fluid Chromatography. Martin Enmark\textsuperscript{1}, Dennis Asberg\textsuperscript{1}, Jorgen Samuelsson\textsuperscript{1}, Hanna Nelander\textsuperscript{2}, Magnus Klarqvist\textsuperscript{2}, Torgny Fornstedt\textsuperscript{1}, \textsuperscript{1}Karlstad University, Karlstad, SWEDEN; \textsuperscript{2}AstraZeneca R&D, Molndal, SWEDEN

4:00 PM Scale-up in Supercritical Fluid Chromatography. Abhijit Tarafder, Christopher Hudalla, Pamela Iraneta, Kenneth Fountain, Waters Corporation, Milford, MA, USA

4:20 PM The Separation of Tashinone IIA by Supercritical Fluid Simulated Moving Bed. Ming-Tsai Liang, Chih-Hsiung Lin, Ru-Chien Liang, I-Shou University, Kaohsiung, TAIWAN

4:40 PM Extraction – Injection (“X-Injection”) as a Solution to the Demands of Sample Introduction in Preparative SFC. Mohamed Shaimei\textsuperscript{1}, Geoffrey Cox\textsuperscript{2}, \textsuperscript{1}PIC Solution SAS, Avignon, FRANCE; \textsuperscript{2}PIC Solution Inc., Rose Valley, PA, USA

5:00-5:10 PM Closing Remarks
• High Efficiency Purification of ω-3-fatty Acids using MCSGP. Friederike Sander, Ingo Piotrowski, Wissenschaftliche Geratebau Dr. Ing. Herbert Knauer GmbH, Berlin, GERMANY

• Polishing of Monoclonal Antibodies using a Polymer Grafted Cation Exchanger. Anna Heijbel, Anna Åkerblom, Jesper Hansson, Bengt Westerlund, Per-Mikael Aberg, Tobias Söderman, Kristina Nilsson-Vällimaa, GE Healthcare, Uppsala, SWEDEN

• Polishing of Biomolecules by Twin-column Counter-current Chromatography (MCSGP). Thomas Muller-Spath, Nicole Ulmer, Lars Aumann, Guido Strohlein, Michael Bavand, ChromaCon AG, Zurich, SWITZERLAND

• Combining Process Science and Engineering to Build a Comprehensive Chromatography Resin Screening Approach. Vani Mathur, Bruno Marques, Kent Goklen, GlaxoSmithKline, King of Prussia, PA, USA

• Solubility Limits in Chromatographic Elution of Proteins: Crystallization Kinetics versus the Mobile Phase Composition. Izabela Poplewska, Wojciech Piatkowski, Dorota Antos, Rzeszow University of Technology, Rzeszow, POLAND

• Purification and Isolation of Proteins in Integrated Processes of Extraction and Chromatography. Wojciech Marek, Roman Bochenek, Renata Muca, Wojciech Piatkowski, Dorota Antos, Rzeszow University of Technology, Rzeszow, POLAND

• Clarification of Solubilized Inclusion Bodies by Permeate-driven Tangential Microfiltration using 1000kDa Membrane. Marc Pompiati, Roche Diagnostics GmbH, Penzberg, GERMANY

• On-column Aggregation of a Recombinant Immunotoxin during Anion Exchange Chromatography. Andrew Fulton, Thomas Linke, Yang Wang, Alan Hunter, MedImmune, Gaithersburg, MD, USA


• Peptisil 10: The New Bulk Silica for Peptide Purification. Imre Salay, Keiji Koyanagi, Oscar Rebolloled, 1DAISO Co. Ltd., Osaka, JAPAN; 2DAISO Fine Chem USA Inc., Torrance, CA, USA

• Automated Purification Group: An Important Functional Group in Merck Discovery Chemistry. Min Liu on behalf of all ACE-AP, Merck & Co., Kenilworth, NJ, USA

• Chromatographer: What Could Modeling do for You? Roger-Marc Nicoud, consultant, Lay Saint Christophe, FRANCE
• The Effect of Taurine on the Relationship Between NO, ADMA and Homocysteine in Endotoxin-mediated Inflammation in HUVEC Cultures. Ozge Tugce Pasaoglu¹, Nurten Turkozkan¹, Mustafa Ark¹, Belgin Polat⁶, Mehmet Agilli³, Halil Yaman³, Gazi University, Ankara, TURKEY; Zekai Tahir Burak Women’s Health Education and Research Hospital, Ankara, TURKEY; Gulhane Military Medicine Academy, Ankara, TURKEY

• Thermal Desorption Extraction for the Determination of Organophosphorus Pesticides in Different Soil Samples a Comparison Between Thermal Desorption and SPE. Enis Macit, Husamettin Gul, Zeki Ilker Kunak, Hakan Yaren, Gulhane Military Medicine Academy, Ankara, TURKEY

• The Effect of Hyperbaric Oxygen Therapy on Neopterin Levels in Rats with Diabetic Ulcer. Emin Ozgur Akgul, Ziya Bayrak, Yasemin Gulcan Kurt, Ibrahim Aydin, Mehmet Agilli, Fevzi Nuri Aydin, Enis Macit, Bülent Uysal, Onder Onguru, Ahmet Korkmaz, Halil Yaman, Gulhane Military Medical Academy, Ankara, TURKEY

• SMB Process with Internal Recycle to Produce Pure Product Stream of Desired Enantiomer from Complex Mixture. Dawid Kiwala¹, Dorota Antos², Andreas Seidel-Morgenstern¹, Max Planck Institute for Dynamics of Complex Technical Systems, Magdeburg, GERMANY; Rzeszow University of Technology, Rzeszow, POLAND

• High Throughput Optimization Approach for Single Step Polishing of Monoclonal Antibodies Post Protein A Capture. Aleksandar Cvetkovic¹, Amitava Kundu², Rene Gantier¹, Pall Life Science, Westborough, MA, USA; Genmab MN Inc., MN, USA

• Molecular Simulations to Predict Adsorption Process Parameters. Diana Khashimova, Hamburg University of Technology, Tashkent, UZBEKISTAN

• Spermine Sepharose as a Clustered-charge Anion Exchange Adsorbent. Sagar Dhamane¹, Federico Ruiz-Ruiz², Mohan-Vivekanandan Poongavanam¹, Katerina Kourentzi¹, Jorge Benavides², Marco Rito-Palmares², Richard Willson¹, University of Houston, Houston, TX, USA; Centro de Biotecnologia FEMSA, Monterrey, MEXICO

• Open-access-based Solution for Target Compound Isolation using the Agilent Walk-up and the Purification Software. Pierre Penduff¹, Andreas Tei¹, Helmut Schulenberg-Schell¹, Ronald Guilliet², Agilent Technologies, Waldbronn, GERMANY; Agilent Technologies, Middelburg, NETHERLANDS

• The Benefits of Continuous Downstream Processing. Sascha Keller, Sandoz Biopharmaceuticals, Kundl, AUSTRIA

• Novel Flowthrough Platform for Virus Purification. Cristina Peixoto¹, Piergiuseppe Nestola¹, Ricardo Silva¹, Louis Villain², Manuel J.T. Carrondo¹, Jose P.B. Mota¹, IBET, Oeiras, PORTUGAL; Sartorius Stedim Biotech, Gottingen, GERMANY
• Operational Process Study Concentrating on Designs for CO2 Recycling for Preparative SFC Systems. John Whelan, Waters Corporation, New Castle, DE, USA

• Development and Scale-up of the Recovery and Purification of a Domain Antibody Fc Fusion Protein - Comparison of a Two and Three-step Platform Approach. Matthew Conover\textsuperscript{1}, Sibyle Herzer\textsuperscript{1}, Atul Bhangale\textsuperscript{1}, Gregory Barker\textsuperscript{1}, Isha Chowdhary\textsuperscript{1}, Wallace Kaserer\textsuperscript{1}, Brian O'Mara\textsuperscript{1}, Nicole Payonk\textsuperscript{1}, Lily Tsang\textsuperscript{1}, Shi-Yu Wang\textsuperscript{1}, Yan Yao\textsuperscript{1}, Siegfried Rieble\textsuperscript{1}, \textsuperscript{1}Bristol-Myers Squibb, Pennington, NJ, USA; \textsuperscript{2}The University of British Columbia, Vancouver, CANADA

• Evaluation of Charged Surface Hybrid Stationary Phases for Medicinal Chemistry Purifications. Shawn Ayube, Larry Miller, Amgen, Cambridge, MA, USA

• Simulated Moving Bed Chromatography for Separations of Nuclear Fuel. Balamurali Sreedhar\textsuperscript{1}, David Hobbs\textsuperscript{2}, Yoshiaki Kawajiri\textsuperscript{1}, \textsuperscript{1}Georgia Institute of Technology, Atlanta, GA, USA; \textsuperscript{2}Savannah River National Laboratory, Aiken, SC, USA

• Mechanistic Insights into Protein Ion-exchange Adsorptive Separations using Single-molecule, Super-resolution Imaging. Mohan-Vivekanandan Poongavanam\textsuperscript{1}, Lydia Kisley\textsuperscript{2}, Jixin Chen\textsuperscript{2}, Andrea Mansur\textsuperscript{1}, Sergio Dominguez Medina\textsuperscript{1}, Eliona Kulla\textsuperscript{1}, Marci Kang\textsuperscript{1}, Bo Shuang\textsuperscript{1}, Katerina Kourentzi\textsuperscript{1}, Sagar Dhamane\textsuperscript{1}, Christy Landes\textsuperscript{2}, Richard Willson\textsuperscript{1}, \textsuperscript{1}University of Houston, Houston, TX, USA; \textsuperscript{2}Rice University, Houston, TX, USA

• Diversity Within the ODS Modified Silica Gel Family. Koyanagi Keiji\textsuperscript{1}, Sallay Imre\textsuperscript{2}, Oscar Rebolledo\textsuperscript{2}, \textsuperscript{1}DAISO CO. LTD., Hyogo, JAPAN; \textsuperscript{2}DAISO CO. LTD., Osaka, JAPAN; \textsuperscript{3}DAISO FINECHEM USA, Torrance, CA, USA

• Extending the Range of Supercritical Fluid Chromatography by use of Water-rich Modifiers. Jinchu Liu, Erik Regalado, Ingrid Mergelsberg, Christopher Welch, Merck & Co., Rahway, NJ, USA

• Experimental Productivity Rate Optimization of Rare Earth Element Separation through Preparative Solid Phase Extraction Chromatography. Hans-Kristian Knutson, Lund University, Lund, SWEDEN

• Application of High Throughput Screening in the Downstream Process Development of a PEGylated Protein - A Case Study. Manju Kuruganti, Brian O'Mara, Zhong-Hua Gao, Pauline Bariola, Crystal Welch, Robert Mallet, Karen De Jongh, Bristol-Myers Squibb, Seattle, WA, USA

• Purification of Antibodies by Precipitating Impurities Using Additives to Enable a Two-Chromatography Step Process. Ji Zheng, Lu Wang, Reb Russell, Michelle Wang, Bristol-Myers Squibb, Bloomsbury, NJ, USA

• Custom Preparative HPLC Systems. Marcus Zyla\textsuperscript{1}, Jim Schools\textsuperscript{2}, \textsuperscript{1}LABOMATIC, Allschwil, SWITZERLAND; \textsuperscript{2}Zinsser NA, Northridge, CA, USA

• Custom Liquid Handling for Prep LC. Marcus Zyla\textsuperscript{1}, Jim Schools\textsuperscript{2}, \textsuperscript{1}LABOMATIC, Allschwil, SWITZERLAND; \textsuperscript{2}Zinsser NA, Northridge, CA, USA
• **Comparison of Protein and VLP Adsorption in Monoliths and in Columns Packed with Large-Pore Particles.** Yige Wu¹, Jared Simons², Dicky Abraham², Giorgio Carta¹, ¹University of Virginia, Charlottesville, VA, USA; ²Merck & Co., Inc., West Point, PA, USA

• **Comparison of Protein Adsorption and Transport on Two Multimodal CEX Resins.** Mimi Zhu, Giorgio Carta, University of Virginia, Charlottesville, VA, USA

• **Sartobind® Membrane Adsorbers in Polishing Applications.** Stefan Fischer-Fruehholz, Gregory Krueger, Sarstock, Goettingen, GERMANY

• **Ligand Density Variations of Fractogel EMD TMAE: Influence on Protein Binding.** Simon Kluters¹, Jan Konrad¹, Lothar Jacob², Heiner Graalfs¹, Christian Frech¹, ¹University of Applied Sciences Mannheim, Mannheim, GERMANY; ²Merck KGaA, Darmstadt, GERMANY

• **Characterization of a Novel Salt Tolerant Anion Exchanger.** Satoshi Fujii, Yuji Kubo, Shigeru Nakatani, Koji Nakamura, Tosoh Corporation, Shunan, JAPAN

• **On-Column Unfolding and Aggregation of a Glycosylated Monoclonal Antibody in Columns Packed with Different CEX Resins.** Jing Guo, Giorgio Carta, University of Virginia, Charlottesville, VA, USA

• **Modeling of Dual Gradient Chromatofocusing in Ion Exchange and Multi-Modal Chromatography.** Yi Feng Lee¹, Heiner Graalfs², Christian Frech¹, ¹University of Applied Sciences Mannheim, Mannheim, GERMANY; ²Merck KGaA, Darmstadt, GERMANY

• **Creation of a Predictive Model and Concise Set of Mixed-mode Ligands to Facilitate Development of Multimodal Chromatographic Separations.** James Woo¹, Hong Chen², Russell Frost², Mark Snyder², Steven Cramer¹, ¹Rensselaer Polytechnic Institute, Troy, NY, USA; ²Bio-Rad Laboratories, Hercules, CA, USA

• **Countercurrent Tangential Chromatography for Purification of Monoclonal Antibodies.** Oleg Shinkazh¹, Andrew Zydney², ¹Chromatan Corporation, State College, PA, USA; ²Penn State University, State College, PA, USA

• **Anion Exchange Chromatography: From Resin Screening to Manufacturing Process.** Patricia Rowicki, John Gavin, Sunitha Kandula, Nihal Tugcu, Thoma Linden, Merck, Kenilworth, NJ, USA

• **Characterization of the Product Related Impurities of an Fc Fusion Protein and Rational Design of a Robust Downstream Purification Process.** Chao Huang, Xuankuo Xu, Udesh DeSilva, Mi Jin, Zhengjian Li, Bristol Myers Squibb, East Syracuse, NY, USA

• **Efficient Separation of Antibody using FcR-based Affinity Resin.** Teruhiko Ide, Toru Tanaka, Yoshiharu Asaoka, Yousuke Terao, Naoki Yamanaka, Kizu Natsuko, Tosoh Corporation, Ayase, JAPAN
• **Novel Small Particle Polymer Media for Process-Scale Protein Separation.** Kazuhiko Tokunaga¹, Noriyuki Yasuda¹, Yoshito Fukuda¹, Shinya Nozaki¹, Shouhei Ohara¹, Masato Towata¹, Masahiko Ishitobi¹, Shouya Yoda², Seigo Miyachi², Nozomi Itou², Masashi Yamanashi², Tadashi Adachi¹, ¹Mitsubishi Chemical Corporation, Kitakyushu, JAPAN; ²Mitsubishi Chemical Group, Yokohama, JAPAN

• **Methodical Guide for Stationary Phase Selection for Early-Discovery Peptide Analysis and Process-Scale Peptide Purification by HPLC.** Oscar Rebolledo¹, Imre Sallay², Keiji Koyanagi³, Junichi Kadoya³, ¹DAISO Fine Chem USA, Inc., Torrance, CA, USA; ²DAISO Co. Ltd., Osaka, JAPAN; ³DAISO Co. Ltd., Amagasaki, JAPAN