# *Recovery of Biological Products X*

## *American Chemical Society, Division of Biochemical Technology*

*Hilton Cancun Beach & Golf Resort, Cancún, Quintana Roo, Mexico*
*3-8 June, 2001*

### *Co-Chairs*

*Steven Cramer, Rensselaer Polytechnic Institute, USA*
*John Curling, John Curling Consulting AB, Sweden*
*Ann Lee, Merck & Co., Inc, USA*

*Sunday, 3 June*

### *Keynote Address*

***The Biotechnology Industry in the 21st Century***
*G. Steven Burrill, Burrill & Company, USA*

*Monday, 4 June*

### *Lessons from the Past*

### *Session Chairs*

*Clark Colton, Massachusetts Institute of Technology, USA*
*Michael Hoare, University College London, UK*

***The Development of Gel Media and Columns for Large Scale Chromatography of Proteins, a Historical Review and Visions for the Future***
*Jan-Christer Janson, Uppsala University, Sweden*

***Membrane Filtration for Biotechnology: Past Experience and Future Directions***
*Georges Belfort, Rensselaer Polytechnic Institute, USA*

***Advances in Industrial Separations - Lessons for Tomorrow's Industry***
*Stephen Drew, Princeton University, USA*

### *Molecular science of Bioseparations*

### *Session Chairs*

*Christopher Lowe, University of Cambridge, UK*
*Todd Przybycien, Carnegie Mellon University, USA*

***Characterization of Protein Interactions and Application to Separations***
*Abraham M Lenhoff, P.M. Tessier, and S.I. Sandler University of Delaware, USA*

***Conformation and a New Modeling Approach to Hydrophobic Interaction Chromatography***
*Erik Fernandez, T. Tibbs, J. Sokol, and J. O'Connell, University of Virginia, USA*

***Stabilization of Proteinaceous Affinity Ligands to Meet Demands in Large-Scale Purification Processes***
*Susanne L. Gulich, M. Nygren Linhult, P-A. Uhlen, and S. M. Hober, Royal Institute of Technology, Sweden*

***Investigation of Internal Protein Transport into Porous Adsorbents by Confocal Laser Scanning Microscopy***
*Jörg Thömmes, T. Linden, M. Halfar, and A. Ljunglöf (2), Heinrich-Heine University, Germany, (2) Amersham Pharmacia Biotech, Sweden*

### *Learning for the future*

### *Session Chairs*

***Barry Buckland, Merck & Co., Inc., USA***
*Abraham Lenhoff, University of Delaware, USA*

***Future Perspectives on Cell and Tissue Engineering***
*Martin Yarmush, Harvard Medical School, USA*

***Life on the Edge: Using Genome-Scale in Silico Models of Microorganisms to Interpret and Predict Metabolic Phenotypes***
*Bernhard O. Palsson, University of California-San Diego, USA*

***DNA Microarray Devices for the New Genomics Revolution: Molecular Diagnostic, Pharmacogenomic and Drug Discovery Applications***
*Michael J. Heller, Nanogen, Inc., USA*

### *Panel Discussion*

***Impact of Genomics/Proteomics on the Future of the Biotechnology Industry***
*Charles Cooney (Moderator), Massachusetts Institute of Technology, USA*
*Martin Yarmush, Harvard Medical School, USA*
*Bernhard O. Palsson, University of California-San Diego, USA*
*Michael J. Heller, Nanogen, Inc., USA*

*Tuesday, 5 June*

### *Unit Operations I*

### *Session chairs*

*Robert van Reis, Genentech, Inc., USA*
*Andrew Zydney, University of Delaware, USA*

***Crystallisation for Selective Microbial Protein Recovery: Use of Surfactants for Enhanced Recovery***
*Michael Hoare, C. Jacobsen (2), J. Garside (3), and A.J. Dorward, University College London, UK, (2) Novo Nordisk A/S, Denmark, (3) UMIST, UK*

***High Gradient Magnetic Fishing: A Robust and Scale-Flexible Approach to Macromolecule Purification***
*Owen R.T. Thomas, S. Justesen, and A. Heeboll-Nielsen, Technical University of Denmark, Denmark*

***Development of a Novel, Direct Refolding Method Using Expanded Bed Adsorption Chromatography***
*Eyn Kyu Lee, T.H. Cho, and C.W. Suh, Hanyang University, Korea*

***Engineering Proteins to Facilitate their Recovery in Aqueous Two-Phase Extraction Systems***
*John K Kan, A. Collén (2), T. Hyytiá (3), J. v. d. Laan, M. Penttilä (3), M. Kula (4), K. Selber (4), H. Stålbrand (2) , M. Ward, and F. Tjerneld (2), Genencor International, Inc., USA, (2) Lund Univeristy, Sweden, (3) VTT, Finland, (4) Heinrich-Heine Universität Düsseldorf, Germany*

## *Unit Operations II*

### *Session chairs*

*Lars-Erik Nyström, Amersham Pharmacia Biotech Ltd., Sweden*
*Shuichi Yamamoto, Yamaguichi University, Japan*

***Membrane Chromatography of Nanometer-Sized Bioparticles***
*Mark R. Etzel, J. Fischer, and H. Yang; University of Wisconsin-Madison, USA*

***Development of Multi-modal Ligands for Capture of Bio-molecules in High Salt Milieu***
*Liv Johansen, M. Belew, S. Eriksson, G. Glad, B.-L. Johansson, O. Lind, J.-L. Maloisel, and N. Norrman, Amersham Pharmacia Biotech, Sweden*

***A Modelling Approach to Process Chromatography***
*Ernst Hansen, and I. Mollerup, Novo Nordisk A/S, Denmark*

## *Workshops*

## *Early Processing Steps*

### *Session chairs:*

*Howard Chase, University of Cambridge, UK*
*Bo Mattiasson, University of Lund, Sweden*

***Selective Recovery of Proteins Using Foam Fractionation***
*Rajni Hatti-Kaul, S. Fernandes, and B. Mattiasson, Lund University, Sweden*

***EBA-Successful Process Development from Feasibility Study to Large Scale Application***
*Jan Feuser, Boehringer Ingelheim Pharma KG,Germany*
***Continuously Operable Rotary Drum Vacuum Filter***
*Antti Kosola, S. Ekbom, and R. Braun, Genencor International, Inc., Finland*

***Technical Investigation of Detergent Based Aqueous Two-Phase Extraction***
*Klaus Selber, M.-R. Kula (2), and M. Penttilä (3), Bayer AG, Germany, (2) University of Duesseldorf, Germany, (3) VTT, , Finland*

***Clarification of E. coli Lysate by Depth Filtration***
*Mindy Wan, S. Rabideau, Y. Wang, J. Schrimsher, and R.W. Moreadith, Covance Biotechnology Services, Inc., USA*

## *Chromatographic Technology*

### *Session chairs:*

*Edwin Lightfoot, Univeristy of Wisconsin, USA*
*Michael Ladisch, Purdue University, USA*

***Evaluation of Models for Scale-up of Compressible Column Packing***
*Erik J. Fernandez, J.E. Maneval (2), A. Howes, K. Ostergren (3), and E.J. Fernandez, University of Virginia, USA, (2) Bucknell University, USA, (3) Lund University, Sweden*

***Recording a 'Fingerprint' of the Packing of a Production Sized Chromatography Column***
*Martin J. Hofmann, Euroflow, UK*
***A Novel Affinity Monolith with Tailored Pores and Ligand Density; Improvement of Ligand Utilisation and Mass Transport Properties***
*Alois A. Jungbauer, and R. Hahn, University of Agricultural Sciences, Austria*

***Numerical Estimation of Multicomponent Adsorption Isotherms: Accuracy and Robustness***
*Ajoy Velayudhan, and L. Zhang, Oregon State University, USA*

***Non-Idealities in Chromatographic Practice***
*Edwin N. Lightfoot, T. W. Root, J. S. Moscariello, and M. A. Teeters, University of Wisconsin, USA*

## *Membrane Bioseparations*

### *Session chairs:*

*Vinay Goel, Millipore Corp., USA*
*Timothy Gregory, Genentech, Inc., USA*

***Investigation of Membrane Chromatography Systems for Purification of Proteins***
*Landon M. Steele, M.M. Heng, and L. Steele, Genencor International, Inc., USA*

***Optimisation of Bioproduct Recovery Using Novel Dynamic Microfiltration Technology***
*Jon Postlethwaite, G. Leach (2), and G.J. Lye, University College London,England, (2) Pall Europe Ltd, UK*

***Downstream Processing of Bovine Lactoferrin from Sweet Whey***
*Roland Ulber, K. Plate, T. Weiss, W. Demmer(2), H. Buchholz(3) and T. Scheper, University of Hannover, Germany, (2) Sartorius AG, (3) Biolac GmbH*

***Affinity Membranes for Immunoglobulin Recovery: A Comparative Study***
*MookambesA.Vijayalakshmi, Y. Coffinier, E. Nedonchelle, O. Pitiot, and C. Legallais, University of Technology Compiegne, France*

***Techniques for Controlling Polysorbate 80 During Ultrafitration of Virus-Like Particles***
*Michael Kosinski, J. Klein, K.Chastain, J.Gawlik, W.Manger, A.Lee, and S.Gadam, Merck & Co., Inc., USA*

## *Manufacturing and Economic Modelling*

### *Session Chairs:*

*Juan Asenjo, University of Chile, Chile*
*Andrew Ramelmeier, Merck & Co., Inc., USA*

***On-Line Purification of IgG by Expanded-Bed Adsorption***
*Jean-Francois P. Hamel, R. Ohashi (2), and A. Chwistek, M.I.T., USA, (2) M.I.T. and Science University of Tokyo*

***Development of Downstream Concepts for Industrial Enzymes Used in Organic Synthesis***
*Andreas Karau, K. Boldt, C. Wunderlich, E. Ostermann, J. Thömmes (2), and U. Reichert (2), Degussa-Huels AG, Germany, (2) Heinrich-Heine Universität, Germany*

***The Role of Process Simulation in Analyzing and Evaluating Bioprocess Integration Opportunities***
*Demetri P. Petrides, and P. Lagonikos (2), Intelligen, Inc., USA, (2) Schering-Plough Research Institute, USA*

***Modelling, Simulation and Optimization of Chromatographic Processes for Protein Purification***
*Juan Asenjo, C. Shene, and B. Andrews, University of Chile, Chile*

***Manufacturing Considerations in Merck's Multi-Product Biologics Pilot Plant***
*R. Andrew Ramelmeier, V. Valmiki, F. Leu, W. Stobart, and D. Seifert, Merck & Co., Inc., USA*

*Wednesday, 6 June*

## *Industrial Case Studies*

### *Session chairs*

*Stuart Builder, Strategic Biodevelopment, USA*
*Duncan Low, Millipore Corp., USA*

***Rituxan® Story - The Journey of a Chimeric Antibody***
*Wolfgang Berthold, and L. Conley, IDEC Pharmaceuticals Corporation, USA*

***Synagis®: A Strategy for Running in the Commercialization Marathon***
*Gail Folena-Wasserman, Medimmune, Inc., USA*

***Challenges During Technology Transfer of a Second Generation Manufacturing Process for a Multivalent Polysaccharide Vaccine***
*Narahari S. Pujar, L. Dieter, M. Gayton, and A.L. Lee, Merck & Co., Inc., USA*

***The Development of an Integrated Industrial Process for an Enzyme System Used in Eye Surgery***
*P. David Robbins, J. Simpson, G. Forrest, and G.-J. Tsai, Wyeth-Ayerst Research, USA*

## *Post-Approval Process Changes*

### *Session Chairs*

*Milton Hearn, Monash University, Australia*
*Jill Myers, Biogen, Inc. , USA*

***Post-Approval Changes - A Science Based Regulatory Approach***
*Robert Yetter, CBER, FDA, USA*

***Downstream Process Improvements to Meet the Challenge of a Growing Worldwide Market***
*Janet M. Griffiths, Genzyme Corporation, USA*

***Development of an Integrated 2nd Generation Process for Protein X***
*Helena Yeung, and J. Beck, Amgen, Inc., USA*

## *Poster Session*

### *Session Chair*

*Maria-Regina Kula, Heinrich-Heine University, Germany*

## *Chromatography - Elution: Special Elution Conditions*

***Effect of Ca2+ in Eluants for Preparative RPC Purification of an Insulin Analogue***
*Are Bogsnes, Novo Nordisk A/S, Denmark*

***A Priori Design of Low Molecular Weight Displacers Using High Throughput Screening and Quantitative Structure Efficacy Relationship Models***
*Steven M. Cramer, C.B. Mazza, K. Rege, C.M. Breneman, and J. Dordick, Rensselaer Polytechnic Institute, USA*

***Advantageous Use of Organic Modifiers in Ion-Exchange Chromatography***
*Arne Staby, Novo Nordisk, Denmark*

## *Chromatography - Materials: New Materials and Characterization of Materials*

***Characterization of New Stable Polymeric Tentacle Chromatography Beads for Fast Production Scale Ion Exchange Chromatography***
*Lothar Britsch, A. Heinen-Kreuzig, and H. Herbert, Merck KGaA, Germany*

***Characterization of New Multi-Modal Separation Media for Capture of Negatively and Positively Charged Biomolecules at High Salt Conditions***
*Ola Lind, B.-L. Johansson, M. Belew, S. Eriksson, G. Glad, L. Johansen, O. Lind, J.-L. Maloisel, and N. Norrman, Amersham Pharmacia Biotech, Sweden*

***Design of a New Chromatography Base Matrix for Future Purification Scenarios***
*Gunnar Malmquist, and A. Bergenstrahle, Amersham Pharmacia Biotech, Sweden*

***The Designs of Resins for Biochromatography***
*Egbert Mueller, K. Nakamura (2), and H. Moriyama (3), Tosoh Biosep GmbH, Germany, (2) Tosoh Nanjo Research Laboratory, Japan, (3) Tosoh Separation Center, Japan*

## *Chromatography - Operation: Chromatography as a Unit Operation*

***Continuous Purification of a Clotting Factor IX Concentrate by Preparative Annular Chromatography***
*Andrea Buchacher, G. Iberer (2), H. Schwinn (3), and D. Josic (3), Octapharma Pharmazeutika Produktionsge s.m.b.H., Austria, (2) University of Agricultural Sciences, Vienna Austria, (3) Octapharma Pharmazeutische ProduktionsGes.m.b.H, Austria*

***Packing and Testing Large Self-Packing Chromatography Columns***
*Stuart R. Gallant, R. Carrillo, K. Brisack, C. Olson, and M. Snyder, Bayer, Corporation, USA*

***Two Chromatography Steps Integrated in One Column***
*Alois Jungbauer, University of Agricultural Sciences, Austria*

***Theory and Practice for Packing Optimal Rolled, Continuous Stationary Phase Columns***
*Michael R Ladisch, C. Li, C.M. Ladisch, R. Hendrickson, C. Keim, N. Mosier, and Y.Yang (2), Purdue University, USA, (2) Institute of Textile Technology, USA*

***Use of a Real-Time Expert System to Assess Packed Bed Integrity in Large-Scale Chromatography Columns***
*Tina M. Larson, Genentech, Inc., USA*

***Opportunities for SMB Technology in Biopharmaceutical Industries***
*Maarten Pennings, M. Bisschops, and M. Oomen, BIRD Engineering, The Netherlands*

***Application of CIM Monolithic Columns for Fast Monitoring and Preparative Purification***
*Ales Podgornik, M. Barut, J. Jancar, M. Merhar, and A. Strancar, BIA Separations d.o.o., Slovenia*

## *Chromatographic Theory: Modelling and Basic Studies*

***Molecular Recognition in Hydroxyapatite Chromatography and Ion Exchange Chromatography of Proteins***
*Takashi Ishihara, and S. Yamamoto, Yamaguchi University, Japan*

***Effects of Particle Structure on Protein Transport and Retention in Ion Exchange Media***
*Abraham M Lenhoff, S.R. Dziennik, E.B. Belcher, and S. Fernandez, University of Delaware,USA*

***Model Assisted Development and Optimization of a Chromatographic Separation of Whey Proteins***
*J0rgen M. Mollerup, and L. Pedersen, Technical University of Denmark, Denmark*

***A "Phase" Diagram for Protein Behavior on Hydrophobic Chromatography Media***
*Todd M. Przybycien, S.M. Cramer (2), and S.U. Sane (3), Carnegie Mellon University, USA, (2) Rensselaer Polytechnic Institute, USA, (3) Genentech, Inc., USA*

***Protein Retention in HIC- Towards a Thermodynamic Framework***
*Abhinav A. Shukla, L. Sorge, J. Boldman, L. Phan, D. Vetterlein, C. Bransford, L. Paul, D. Thompson, and S. Waugh, Immunex Corporation, USA, (2) ICOS Corporation, USA*

## *Expanded Bed Adsorption*

***Ligand Choice in EBA Purifications of Recombinant Proteins***
*Howard A. Chase, R.H. Clemmitt, and N. Abdullah, University of Cambridge, UK*

***Separations of Monocytes and Stem Cells from Human Blood Using Immuno-Affinity Expanded Bed Adsorption***
*Robert H. Clemmitt, L.B. Ujam, and H.A. Chase, University of Cambridge, UK*

***Efficiency of Density-Enhanced Wash Steps in Expanded Bed Adsorption***
*Conan J. Fee, University of Waikato, New Zealand*

***Expanded Bed Absorption of Whey Immunoglobulins using a Stainless Steel/Agarose Matrix Derivatised with a Highly Selective Mixed Mode Ligand***
*Marie Bendix Hansen, M. Olander, and A. Lihme, UpFront Chromatography, Denmark*

***A Comparison of Hydrodynamic Properties of Large Scale Expanded Bed Adsorption Columns***
*Timothy J. Hobley, A. Heeb0ll-Nielsen, J.J. Hubbuch, and O.R.T. Thomas, Technical University of Denmark, Denmark*

***Use of Expanded Bed Chromatography for Purification of Group-Specific Polysaccharide from Fermenter Cultures of Group A Neisseria Meningitidis***
*RobertL. Hopfer, G. Huckaby, S. Doares, C.W. Elton (2), P. McCauley, E. Alegria , S. Bauer, and C. Mitchel, Wyeth Vaccines, USA, (2) East Carolina University, USA*

***A New Fluid Distribution System for Scale-Flexible Expanded Bed Adsorption***
*Juergen Josef Hubbuch, A. Heeboll-Nielsen, T.J. Hobley, and O. R.T. Thomas, Technical University of Denmark,Denmark*

***Expanded Bed Adsorbtion as a Primary Recovery Step for the Isolation of the Insulin Precursor MI3***
*Ole E. Jensen, P. Brixius (2), I. Mollerup, M.-R. Kula (2), and J. Thömmes (2), Novo Nordisk, Denmark, (2) Heinrich-Heine University, Germany*

***Process Design in Expanded Bed Adsorption -- Integration of Biomass Influence into Optimizing Operation Conditions***
*M.-R. Kula, D.-Q. Lin, E. Knieps, U. Reichert, and J. Thömmes, Heinrich-Heine University, Germany*

***Recovery and Purification of the Protective Antigen from B. anthracis using Expanded Bed Adsorption on a Hydrophobic Matrix***
*Joseph Shiloach, and D. Ramirez, National Institutes of Health, USA*

## *Gene Therapy/Plasmid, Virus and Nucleic Acid Purification*

***Rationalized Methods for the Purification of Plasmids for Gene Therapy: Chromatography and Liquid Extraction***
*Barbara Andrews, Z. Gerdtzen, and J. Asenjo, University of Chile, Chile*

***Engineering Challenges in the Production and Purification of First and Third Generation Adenovirus Vectors for Gene Therapy***
*Juan Asenjo, University of Chile, Chile*

***Rapid Adenovirus Purification using Q Sepharose XL***
*Kjell O Eriksson, E.A. Olmsted (2), J. Palladino (2), and A.R. Davis (2), Amersham Pharmacia Biotech, USA, (2) Baylor College of Medicine, USA*

***Design and Assembly of Solid Phases for the Effective Recovery of Nanoparticulate Bioproducts in Fixed and Fluidised Bed Contactors***
*Andrew Lyddiatt, Z. Zhang, S. Burton, S. Williams, and E. Thwaites, University of Birmingham, UK*

***Purification of Plasmid DNA by Selective Salt Precipitation***
*Patrick M. McHugh, and M. Hoare, University College London, UK*

***Purification of a Cystic Fibrosis Plasmid Vector for Gene Therapy using Hydrophobic Interaction Chromatography***
*Duarte Miguel Prazeres, M.M. Diogo, and J.A. Queiroz (2), Instituto Superior Tecnico, Portugal, (2) Universidade da Beira Interior, Portugal*

***Continuous Purification of Plasmid DNA Using Preparative Continuous Annular Chromatography***
*Adalbert Prior, J. Wolfgang, F. Blanche (2), and M. Couder (2), Prior Separation Technology GmbH, Austria, (2) Aventis Pharma, France*

***Sequence-Specific DNA Purification Using PNA Amphiphiles***
*James W. Schneider, J. Vernille, and B. Armitage, Carnegie Mellon University, USA*

***Design of Expanded Bed Supports for the Recovery of Plasmid DNA by Anion Exchange Adsorption***
*Owen R.T. Thomas, and I. Theodossiou, Technical University of Denmark, Denmark*

***Purification of Plasmids, Viral Vectors, and Oligonucleotides by Membrane Chromatography***
*Tim N. Warner, S. Nochumson, P. Kostel, and Y. Yang, Pall BioPharmaceuticals, USA*

***Immobilized-Metal Affinity Separation of Nucleic Acids***
*Richard C. Willson, J.C. Murphy, and D. Jewell, University of Houston, USA*

## *Ligands: Selection and Characterization of New Affinity Ligands*

***Synthetic Ligand Affinity Adsorbents for Highly Selective Purification of Human Plasma Proteins***
*Dev Baines, M. Burton, J. Pearson, S. Burton, and J. Curling, ProMetic BioSciences, UK*

***Scale-Up and Characterization of an Affinity Chromatography Resin Employing a Polypeptide Ligand for Purification of Factor VIII***
*Brian D. Kelley, J. Booth, M. Tannatt, S. Hagelberg (2), and R. Magnusson (2), Genetics Institute, USA, (2) Pharmacia Corporation, Sweden*

***A New Approach for the Development of a High Performance Peptide Affinity Matrix for Selective Protein Purification***
*Dirk Luetkemeyer, University of Bielefeld, Germany*

***Evaluation of a non-MAb Affinity Ligand for Purification of B-Domain Deleted Recombinant Coagulation Factor VIII***
*Anna Messing Eriksson, R. Magnusson, S. Hagelberg, K. Nord (2), O. Nord (2), P.-A. Nygren (2), C. Ljunqvist, and B.D. Kelley (3), Pharmacia AB, Sweden, (2) Royal Institute of Technology, Stockholm Sweden, (3) Genetics Institute, USA*

***Development of Mammalian Serum Albumin Affinity Purification Media by Peptide Phage Display***
*Aaron K. Sato, D.J. Sexton, Z. Streltsova, E.H.Cohen, L. A. Morganelli, G.P.Conley, S.W. Lee, Q.L. Wu, D.B. DeOliveira, R.C. Ladner, C.R. Wescott, A.C.Ley, and T.C.Ransohoff,, Dyax Corp, USA*

***Identification of Peptide Ligands Generated by Combinatorial Chemistry that Bind Prion Protein***
*Ruben G. Carbonell, Honglue Shen, and D.J. Hammond (2), North Carolina State University, USA, (2) V.I. Technology, USA*

***Application of Self-Cleaving Binding Domains to Affinity Separations***
*David W Wood, G. Belfort, and M. Belfort (2), Princeton University, USA, (2) Rensselaer Polytechnic Institute, USA(3) Wadsworth Center, New York State Department of Health, USA*

## *Monoclonal Antibody Purifcation*

***Non-Protein A Process for Clinical Production of a Monoclonal Antibody***
*Zafeer Ahmad, A. Diener, R. Scott, B. Vickroy, and G. Zapata, SmithKline Beecham Pharmaceuticals, USA*

***Recovery of Human Monoclonal Antibodies from Transagenic Goat Milk***
*Georges Belfort, A. Leverdiere, D. Couto, and G.L. Baruah (2), Genzyme Transgenics Corporation, USA, (2) Rensselaer Polytechnic Institute, USA*

***Large-Scale Purification of Monoclonal Antibodies: Is Protein A Necessary?***
*Deborah B. Kaufman-Follman, and G. Blank, Genentech, Inc, USA.*

***Predictive Evaluation of Chromatographic Media Performance in Process Scale Production of Antibodies***
*Rob Noel, G.D. Kemp, G. Hamilton, G. Proctor, and L Taylor, Millipore UK*

***Optimization of Monoclonal Antibody Production and Purification: Integrating Chemically Defined Cell Culture Medium and a Novel Chromatographic Method***
*Warren Schwartz, D. Judd, M. Wysocki, and P. Santambien, Life Technologies, Inc., USA*

***Purification of Monoclonal Antibodies by Hydrophobic Interaction Chromatography***
*Thomas M. Smith, J. Bodek, and R. Scott, SmithKline Beecham, USA*

## Process: Processes and Process Design

***Purification and Characterization of Recombinant Hepatitis B Surface Antigen Using Annexin V as a Ligand***
*Miladys Limonta Fernández, D. González, V. Lugo, A. Ramírez, O. Amarante, and R. Páez, Center for Genetic Engineering and Biotechnology, Cuba*

***Recombinant Growth Factors Produced with Improved Cleavage of Expressed Fusion Proteins Using a Novel Protease and Peptide Linker***
*Geoffrey L. Francis, J. Wallace (2), L. Graham (3), S. Milner I. Butler, and S. Lien, GroPep Ltd., Australia, (2) University of Adelaide, Australia, (3) CSIRO, Australia*

***The Design and Implementation of an Immobilized Pepsin Column for the Production of Antibody Fragments at Manufacturing Scale***
*Rhona M. O'Leary, D. Narindaray, G. Zapata (2), and G.S. Blank, Genentech, Inc., USA, (2) SmithKline Beecham Pharmaceuticals, USA*

***Expression in Escherichia coli, Purification, Inactivation and Characterization of Recombinant Tat Toxoid From Human Immunodeficiency Virus Type 1***
*Olivier Pitiot, M. Chevalier, F. Boudet, C. Breda, and D. Speck, Aventis Pasteur SA, France*

***Primary Recovery of Therapeutic Proteins from Egg Albumin***
*Thomas C. Ransohoff, TranXenoGen, USA*

***Isolation of Whey Proteins on a 100,000 Liters/day Scale***
*Vinit Saxena, W.K. Nielsen, and S. Ahmed, Sepragen Corporation, USA*

***The Development of a High Performance Cation-Exchange Chromatography Step in the Purification of rhNGF***
*Charles H. Schmelzer, and C. Yedinak, Genentech, Inc, USA.*

***Spike Recovery of Proteins from Egg White***
*Jim Seely, Amgen, Inc., USA*

***Development of a Model Using Statistically Designed Experiments to Predict the Performance of a Purification Process***
*William K. Wang, R.D.J. Chen, E. Wilson, H.W. Klepser, and P.R. McAllister, SmithKline Beecham Pharmaceuticals, USA*

## Refolding of Proteins

***New Chromatographic Methods for the Isolation and Refolding of Proteins from E. coli Inclusion Bodies***
*Jan-Christer Janson, Z. Gu1 (2), M. Weidenhaupt (3), N. Ivanova, M. Pavlov, B. Xu, and Z.-G. Su (2), Uppsala University, Sweden, (2) Chinese Academy of Sciences, China, (3) Institut de Biologie Structurale Jean-Pierre Ebel, France*

***Development of a Continuous Refolding Method with High Refolding Efficiency***
*Shigeo Katoh, Y. Katoh, and M. Farshbaf, Kobe University, Japan*

## Unit Operations: Unit Operations Excluding Chromatography

***Prediction of the Performance of Industrial Centrifuges using Laboratory Scale-Down Models***
*R. Michael Boychyn, S. Yim (2), P.A. Shamlou (2), M. Bulmer (3), J. More (3), and M. Hoare (3), Eli Lilly and Company, USA, (2) University College London, UK, (3) Bio Products Laboratory, UK*

***Crystallization Process Development for the Recovery of Biological Products***
*Sean M. Dalziel, DuPont Central R & D, USA*

***Matching Unit Operations to Plant Hosts for Recovery of Recombinant Proteins***
*Charles E. Glatz, Y. Bai, and T. Menkhaus, Iowa State University, USA*

***Diatomaceous Earth Filtration for Clarification of Yeast Lysates***
*Shishir D. Gadam, A. Leong, A. Lee, and M. Kosinski, Merck & Co., Inc., USA*

***Centrifugal Precipitation Chromatography: Protein Fractionation by Differential Precipitation***
*James T. Hsu, Lehigh University, USA*

***Electrophoresis in Bioprocessing: Challenges and Rewards***
*Cornelius F. Ivory, Washington State University, USA*

***Suspended Bed Chromatography: An Alternative Technique for Large-Scale Chromatography***
*Peter Levison, Whatman International Ltd., uK*

***Development of Cryopreservation as a Scalable Tool for Eliminating Unwanted Changes during the Down Stream Processing of Bio-Engineered Products***
*David F. Sesin, T. Hughes, and R.Wisniewski, Integrated Biosystems, USA*

## Validation: Validation and Special Analytics

***Oncophage® - A Patient Specific Cancer Vaccine: Implications for Process Change, Process Validation and the Comparability Paradigm***
*Neal F. Gordon, Antigenics, Inc., USA*

***Evaluation of Ultraviolet Light Induced Inactivation of Mouse Minute Virus***
*Robert S. Gronke, P. Levy, J.A. Myers, T. Mil (2), D.C. Bomberger (2), K. Mortelmans (2), and N. Mufti (3), Biogen, Inc., USA, (2) SRI International, USA, (3) Inhale Therapeutics, USA*

***Development of a Regeneration Protocol for Anion-Exchange Resins***
*Amitava Kundu, K. Allen, R. Carrillo, M. Snyder, and G. Burton, Bayer, Corporation,USA*

***A Generic Method for Evaluating Product Quality from Fermentors***
*Chuck Olson, J. Mazer, H. Park, M. Zachariou, and M. Snyder, Bayer, Corporation, USA*

***Demonstration of Process Robustness Using Statistical Experimental Designs***
*Frank Riske, N. Troccoli, L. Sherman, and S. Pool, Genzyme, USA*

***Assessing the Impact of Hydrodynamic Forces on Plasmid Genes and Disabled Viruses***
*Parviz Shamlou, P. Lotfian, S. Levy, and R.Coffin, University College London, UK*

***Analysis of Retrovirus and Prion Clearance Using Molecular Approaches***
*Dominick A. Vacante, W-T. Hsieh, R.E. Bird, A. Chang, L. White, A.L. Lemire, D. Evans, and M.E. Wieb, BioReliance Corporation, USA*

*Thursday, 7 June*

## *Gene Therapy/Plasmid and Virus Purification*

### *Session chairs*
*Bob Bridenbaugh, Valentis, Inc., USA*
*Erno Pungor, Berlex laboratories, USA*

***Large-Scale Purification of Plasmid DNA by Triplex Affinity Chromatography***
*Francis A. Blanche, B. Cameron, D. Bisch, and S. Sommariba, Aventis Pharma, France*

***A Novel Non-Chromatographic Purification Process for Plasmid DNA***
*Russel J. Lander, M. Winters, F. Meacle, A. Lee, Merck & Co., Inc., USA*

***Development and Validation of a Recovery and Purification Process for Recombinant AAV-based Gene Therapy Vectors***
*E. Morrey Atkinson, D.J. Debelak, E. Eith, G. Nichols, L. Giugler, and J.R. Weil, Targeted Genetics, USA*

***Analytical Definition of Recombinant Adenoviral Vectors***
*Elisabeth Lehmberg, Berlex Biosciences, USA*

## *Scale Up Challenges for Recombinant BioPharmaceuticals*

### *Session Chairs*
*Inger Mollerup, Novo Nordisk, Denmark*
*Kenneth Taksen, Pfizer, Inc., USA*

***Practical Aspects of Large Scale Protein Crystallization***
*Meng H. Heng, Genencor International, Inc., USA*

***Process Design & Economics for Optimal Manufacturing Scale and Production Strategy***
*Watler, Peter, K., O. Kaltenbrunner, D. Lewis-Sandy, and S. Yamamoto (2), Amgen, Inc., USA, (2) Yamaguchi University, Japan*

***Design and Scale-up of a Monoclonal Antibody Recovery Process***
*Gregory S Blank, Genentech, USA*

***Ton-Scale Production of Recombinant Protein Pharmaceuticals***
*Scott P. Fulton, Genzyme Transgenics Corporation, USA*

## *Keynote Address*

***Moving Downstream Processing Up to the Front***
*Harvey Blanch, University of California, Berkley, USA*

*Friday, 8 June*

## *Process Integration and Optimization*

### *Session Chairs*
*Sam Guhan, Pfizer, Inc., USA*
*Jörg Thömmes, IDEC Pharmaceuticals Corporation, USA*

***Substitution of Protein A Affinity into an Early-Stage Purification Process***
*Jonathan L. Coffman, S. Sun, B. Foster, B. Germain, and J. Robinson, Genetics Institute, USA*

***Process Design, Improvements, Maintenance and Economics***
*John H. Frenz, Genentech, Inc, USA*

***New Ways for Visualising the Performance of Integrated Bioprocesses***

*Nigel J Titchener-Hooker, University College London, UK*

***Cost-Effective Cell-Free Protein Synthesis for Process Integration***
*James R Swartz, D.-M. Kim, N. Michel-Reydellet, and J. Zawada, Stanford University, USA*

## *Combinatorial Technology for Bioseparations*

### *Session chairs*
*Brian Kelly, Genetics Institute, USA*
*Richard Willson, University of Houston, USA*

***Ligands from Combinatorial Peptide Libraries for Virus Detection and Removal***
*Ruben G. Carbonell, J.R. Salm, D.T. Brown, and D.J. Hammond (2), North Carolina State University, USA, (2) V. I. Technologies, Inc, USA*

***Design of Novel Affinity Ligands Towards Porcine Pancreas alpha-Amylase Based on 3D-Pharmacophore Model Analysis***
*Yasuro Shinohara, E. Carredano, U. Tedebark, H. Baumann, H. Andersson, S. Öhrman, C. Lindquist, M. Westerfors, and D. Choudhury (2), Amersham Pharmacia Biotech, Sweden, (2) Biomedical Centre, Sweden*

***Peptide Nucleic Acids and their Application to DNA and mRNA Separations and Microarray Based Analysis***
*Charles A. Haynes, University of British Columbia, Canada*

***Combinatorial Approaches to Ligand Design and Selection for Affinity Chromatography***
*Christopher R. Lowe, University of Cambridge, UK*

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