

## **Recovery of Biological Products VIII**

### **Engineering Foundation**

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

##### **Co-chairs**

Michael R. Ladisch, Purdue University, USA  
Helmut Sassenfeld, Immunex Corporation, USA  
Kenneth G. Taksen, Pfizer Inc., USA

Sheraton El Conquistador Resort & Country Club, Tucson, Arizona, USA  
20-25 October, 1996

Sunday, 20 October

##### **Keynote Address**

###### **Can We Learn from the Past?**

Arthur Humphrey, Pennsylvania State University, USA

Monday, 21 October

##### **Primary Separation Techniques**

###### **Session chairs**

Inger Mollerup, Novo Nordisk A/S, Denmark  
Charles F. Goochee, Chiron Corporation, USA

###### **In Situ Capture of a Recombinant Protein during Large Scale Cell Culture**

Mark Better, R. Richieri, A. Tran, W. C. McGregor, Xoma Corporation, USA

###### **Process Design for the Isolation and Purification of Cholesterol Oxidase from Nocardia Based On A Cloud-Point Extraction.**

Maria-Regina Kula, Torsten Minuth, Jörg Thömmes, Heinrich-Heine University, Germany

###### **Genetic Engineering of Peptide-Protein Fusions for Control of Protein Partitioning In Thermoseparating Aqueous Two-Phase Systems.**

Folke Tjerneld, Kristina Bergren, Lund University, and Andres Veide and Per-Ake Nygren, Royal Insitute of Technology, Sweden

###### **Removal of Mammalian Cells and Fine Cell Debris with The Aid Of Flocculants.**

Jill A. Myers, Peter Levy, Chris Gallo, Biogen, Inc., USA

###### **High Selectivity Purification of Recombinant Proteins from Milk Using Expanded Bed Chromatography**

William Velander and Arthur Degener, Virginia Polytechnic Institute and State University, USA, and Makonnen Belew, Pharmacia Biotech AB, Sweden

###### **Carbon Dioxide Extraction of Proteins**

Eric J. Beckman, E. Ghenciu and A. J. Russel, University of Pittsburgh, USA

##### **Membrane Separations**

###### **Session chairs**

Andrew Zydney, University of Delaware  
Harold Staack, Abbott Laboratories

###### **High Performance Tangential Flow Filtration for Protein Purification.**

Shishir Gadam, Scott Orlando, Ralf Kuriyel and Steven Pearl, Millipore Corporation, Leah Frautschy, Skand Saksena, Elizabeth Goodrich and Robert van Reis, Genentech Inc., and Andrew Zydney, University of Delaware, USA

###### **Protein Recovery from Cell Debris using Membrane Backpulsing**

Robert Davis, University of Colorado, USA

###### **Microfiltration of Recombinant Yeast Employing Novel High-Shear Filtration Systems**

Steven S. Lee, Merck & Co., Inc., USA

###### **Selective Cell Separation with Affinity-Linked Membranes**

Clark K. Colton and Michael J. Pomainek, Massachusetts Institute of Technology, USA

###### **Direct Affinity Membrane Immunoabsorption from Dispersions; an Alternative to Expanded Bed Chromatography**

Elias Klein, Don Yeager and Sabine Waigel, University of Louisville, USA, Egbert Muller and E. Merck, Darmstadt, and Ulrich Baurmeister, Akzo Nobel, Germany

Tuesday, 22 October

##### **Industrial Case Studies**

###### **Session chairs**

Stuart Builder, Genentech, Inc., USA  
John Curling, John Curling Consulting AB, Sweden

###### **Unlocking the Process: Post Regulation Changes to Commercial Bioprocesses**

Jeffrey C. Baker, Eli Lilly & Company, USA

###### **A Case of Continuous Development**

Inger Mollerup, Steen Weber Jensen, Per Larsen, Ole Schou and Leo Snel, Novo Nordisk A/S, Denmark

### **Changing the Process for Activase**

Robert Bridenbaugh, T. McNemey, R. Arnold, J. Cacia, J. Frenz, Genentech, Inc., USA

### **The Large Scale Isolation of Thrombolytic Protein at Abbott Laboratories**

Harold Staack, Abbott Laboratories, USA

### **A Case Study of the Transmission of Hepatitis C by Intravenous Gammaglobulin**

Donald A. Baker, Baxter Biotech, USA

### **Recombinant Therapeutic Protein Recovery from Transgenic Milk**

Michael L. Hayes, Julie S. Pollock, Joseph P. Kutzko and Edward S. Cole, Genzyme Corp., USA

### **Large Scale Purification Process For Recombinant NSlospA as A Candidate Vaccine for Lymes Disease**

Nirdosh K. Puri, Steven R. Caldwell and Jose Varghese, Pfizer Inc., USA

## **Regulatory Topics**

### **Session chairs**

Arindam Bose, Pfizer Inc. USA

Alan R. Goldhammer, Industrial Biotech Association, USA

### **FDA Reform Proposals - How Far Have We Gone?**

Alan R. Goldhammer, Biotechnology Industry Organization, USA

### **FDA Perspective on the Recent Changes in the Regulation of Biotechnology**

Kathryn C. Zoon, US Food and Drug Administration, USA

### **Evolution, Current Status, and Impact of ICH Biotechnology Guidelines**

Gregory C. Davis, Eli Lilly & Co., USA

### **A Historical Perspective on Oversight of Human Gene Therapy, From NIH-RAC to FDA**

Gerald J. McGarrity, Genetic Therapy Inc., USA

### **FDA Approach To Regulation of Human Gene Therapy.**

Bruce Merchant, Merchant/Taylor International, Inc., USA

Wednesday, October 23

## **Chromatography**

### **Session chairs**

Shuichi Yamamoto, Yamaguchi University, Japan

Steven M. Cramer, Rensselaer Polytechnic Institute, USA

Gail Sofer, Pharmacia Biotech, USA

### **Quantitative Characterization of Protein Ion-Exchange Retention, And Implications For Stationary-Phase Selection And Design, And Separations Performance.**

Peter D. de Phillips and A. M. Lenhoff, Merck & Co., Inc., USA

### **Continuous Solid Phase Pegylation of Proteins**

Jill Porter, Christine Cavilhas, Kathleen Prinzo, Carol Schaffer, Seth Monkarsh and Pascal Bailon, Hoffmann-La Roche, USA

### **Troubleshooting & Productivity Optimization of Ion Exchange Chromatography**

Peter K. Watler and Daphne W. Feng, Amgen, Inc., USA

### **Capture Of Proteins by Low Plate Number Systems: Expanded Bed, Membrane Adsorber And Conventional Gel Bed.**

Shuichi Yamamoto, Yamaguchi University, Japan

### **Purification of Human Albumin from Plasma by Membrane Chromatography**

Jörg Thömmes, Klaus H. Gebauer and Maria-Regina Kula, Heinrich-Heine University, Germany

### **Transport Phenomena and Scale up Properties of Rolled Stationary Phases for Rapid Protein Chromatography.**

Michael R. Ladisch, Richard Hendrickson, Ayda Sarikaya, Kent Hamaker, Shian-Lan Rau and Chris Ladisch, Purdue University, USA

### **Application Of Novel Immobilized Metal Ion Affinity Ligands For The Selective Capture And Purification of Proteins.**

Milton T.W. Hearn, Monash University, Australia

### **A Novel One Step Purification of IgG Using a Large Bead Agarose Ion Exchange Resin**

Peter Grandics, Susan Szathmary, Mike Johnson and Warren Chester, Sterogene BioSeparations, Inc., USA

### **Scaling-Up Batch Adsorption with Column**

### **Chromatography for Hepatitis B Purification.**

Michael Kosinski, Dennis Kubek, Robert Sitrin, Diane Krips, William Adams and Wendy Sanford, Merck & Co., Inc., USA

### **Modelling Preparative Chromatography of Heterogeneous Proteins**

Robert D. Johnson and John Frenz, Genentech, Inc., USA

### **Application of Statistical Experimental Design in the Validation of a Chromatographic Process**

Sandra E. Poole, Paula Chabot, Pierre Dubord, Anthony Hawrylechko and Kevin Websdale, Biomira Inc., Canada

### **Capture of Humanized IgG4 Directly From the Fermenter Using Streamline® rProtein A.**

Christina Jägersten and Stefan Johansson, Pharmacia Biotech AB, Rebecca Pardon and Julian Bonnerjea, Celltech Biologics plc, UK

### **Protein Purification from Complex Biological Mixtures Using Low Molecular Weight Displacers in Ion Exchange Systems**

Steven M. Cramer, K. Barnhouse, A. Shukla, Rensselaer Polytechnic Institute, USA

## **Workshops:**

### **Economics of Chromatography Session chairs**

Michael J. Keyes, Pfizer Inc., USA

Scott Wheelright, Scios Nova, USA

**Electrokinetic Separations****Session chairs**

Neil Ivory, Washington State University, USA  
Pier Giorgio Righetti, University of Milano, Italy

**Biochemical Reactions and Separations on a Microchip**

Per Andersson, D. Jed Harrison, Nghia Chiem,  
Thompson Tang, Karl Fluri, Christa Colyer and Paul Li,  
University of Alberta, Canada

**Optimization of Rapid Isoelectric Focusing of Proteins**

Milan Bier, The University of Arizona, A. Ford and R. B. Marquez, Protein Technology, Inc., USA

**Preparative Protein Purification in Multicompartment Electrolyzers with Immobilized Membranes**

Pier Giorgio Righetti and A. Bossi, University of Milano, Italy

**The Gradiflow Approach To Protein Purification**

Garry L. Corthals, Brett Collins, Andrew A. Gooley, Keith L. Williams, Macquarie University, Australia

**Recovery of Gene Therapy Products****Session chairs**

Charles L. Cooney, Massachusetts Institute of Technology, USA  
Jan-Christer Janson, Pharmacia Biotech AB, Sweden

**Purification and Recovery of Gene Therapy Vectors**

David Clark, R. Blakesley, F. Bloom, I. Blumentals, R. Goldin and D. Nelson, Life Technologies, Inc., USA

**Manufacturing of DNA Vectors for Gene Therapy: Process Development and Scale-Up**

Magda Marquet, Nancy Horn, Roya Lahijani, Jennifer Meek and Gregg Budahazi, Vical, Inc., USA

**Process Development for the Production of Adenovirus Vectors**

Jean-Marc Guillaume, Anne Barbot, Sandrine Benoist, Francis Blance, M. Couderc and Nathalie Couteault, Rhône Poulenc Rorer-Gencell, France

**Process Development for Manufacturing of Gene Therapy Vectors: Recovery of Adenovirus and Recombinant Adeno-Associated Virus Vector**

E. Morrey Atkinson, Ian Aranha, Daryn Debelak, Thomas C. Reynolds and Victor P. Fung, Targeted Genetics Corp., USA

**Keynote Address****Awakening of The Dragon: Biotechnology in China (PRC)**

Daniel I. C. Wang, Massachusetts Institute of Technology, USA

**Process Monitoring & Control****Session chairs**

Neal Gordon, PerSeptive Biosystems, Inc., USA  
Michael Hoare, University College London, UK

**Assay Development For Real Time In-Process Monitoring of Biological Products**

Brent R. Larsen, Protein Design Laboratories, Inc., USA

**New Procedures for On Line Monitoring of Proteins and Extracellular Components in Mammalian Cell Cultivation Processes - Particular Application of Biosensors and FIA**

Thomas Scheper, Jörg Hagedorn, Bernd Hitzmann, Gerlinde Kretzmer and Roland Ulber, Institut für Technische Chemie, Germany

**Rapid Monitoring for the Enhanced Piloting and Control of Protein Recovery and Purification Processes**

Michael Hoare, University College London, UK

**Poster Sessions****Session Chair**

M.-R. Kula, Heinrich-Heine University, Germany

**Early Steps, Integral Approaches****Heat Treatment of Crude Lysate Streams from E. Coli Fermentations in the Recovery of Intracellular Recombinant Proteins**

Mark Chivers, Thomas K. Belval, James R. Ryland, Somatogen, Inc., USA

**Production of Savinase from Bacillus Lentus in a Membrane-Recycle Bioreactor**

Stig Lykke Iversen, The Technical University of Denmark, Denmark

**Direct & Efficient Product Capture from Unclarified, Disrupted or Whole Cell Broths Using Chromatographic Membrane**

Vinit Saxena, Vikram Gossain, Sanjeev Saxena, Sepragen Corporation

**Recovery of Taxol in Continuous Recirculation Process**

Shintaro Furusaki, Chiharu Ohzora and Minoru Seki, University of Tokyo, Japan

**Use of Physico-Chemical Properties of Proteins for the Selection of Purification Processes; Development of an Expert System**

Juan A. Asenjo, F. Vazquez, C. Garrido, M. E. Lienqueo and B. A. Andrews, University of Chile, Chile

**Simulation and Scale Down for the Rapid Design of Integrated Bioprocesses**

N. J. Titchener-Hooker, University College London, UK

**Use of the Green Fluorescent Protein for Screening Separation Processes based on a Novel Metal Chelating Affinity Tag**

Erwin Flaschel, Ludger Poppenborg, Ralf Neitzel and Karl Friebs, University of Bielefeld, Germany

## **Extraction of Proteins**

### **Kinetics of Phase Separation and Correlations for Predicting the Partition Behavior of Proteins in Aqueous Two-Phase Systems**

Barbara Andrews, J. A. Asenjo, A. Kaul and M. Salamanca, University of Chile, Chile

### **Charge Effects in Protein Partitioning in Aqueous 2-Phase Systems**

Charles E. Glatz, Weiyu Fan and Ufuk Bakir, Iowa State University, USA

### **Carbon Dioxide Extraction of Proteins**

Landon M. Steele and N. T. Becker, Genencor International, E. Ghenciu, A. J. Russel and E. J. Beckman, University of Pittsburgh, USA

### **Electroextractive Separation of Proteins from Cell Debris**

William Clark and Ryan D. Oehler, Worcester Polytechnic Institute, USA

## **Expanded Bed Adsorption**

### **Recovery of a Recombinant Protein from CHO Cell Culture by Expanded Bed Adsorption; Analysis of Operating Parameters and Scale-Up**

Joanne T. Beck, Stridhar Viswanatha, Craigh Emery and Stuart E. Builder, Genentech, Inc., Alisa Liten, Pharmacia Biotech Inc., USA, and Annika Lindgren Pharmacia Biotech AB, Sweden

### **Expanded Bed Purification of Proteins - Latest Developments**

Howard A. Chase, Siddhartha Ghose, Ryan O. Owen, Robert H. Clemmit and Graham E. McCreath, University of Cambridge, UK

### **Scale Down and Methods Development for Expanded Bed Chromatography of Proteins**

Siddhartha Ghose and Howard Chase, University of Cambridge, UK

### **The Influence of Operating Conditions and Material Properties on the Adsorption Performance in Fluidized Beds**

Maria-Regina Kula, Andreas Karau and Jörg Thömmes, Heinrich-Heine University, Germany

### **Direct Capture of Monoclonal Antibodies Using a New Protein A Matrix in Fluidized Bed Chromatography under Lysis Free Conditions**

Dirk Lütkemeyer, N. Ameskamp, H. Tebbe, J. Wittler and J. Lehmann, University Bielefeld, Cell Culture Technology, Germany

### **Recovery of Mutant Diphtheria Toxin Using Expanded Bed Chromatography**

Joseph Shiloach and Jeanne Kaufmann, National Institutes of Health, USA

### **Integration of Fluidized Beds with Batch Fermentation: Design, Assembly and Evaluation of Customized Adsorptive Supports**

Andrew Lyddiatt, Zhanren Zhang, Michael Burns, Gordon Gilchrist, Grant Hamilton, Deidre O'Sullivan and Ewan Robertson, University of Birmingham, UK

## **Chromatography (New Materials)**

### **Characterization of a New Tentacle Based Size Exclusion Support and its Use for the Preparative Polishing of a Humanized Recombinant Immunoglobulin Fusion Protein**

Lothar Britsch and W. Brümmer, Merck KgaA, Germany

### **Synthesis and Characterization of High Porosity Polymeric Supports for Large Scale Perfusion Chromatography**

Duncan Whitney, N. Mu, M. McCoy and N. Afeyan, PerSeptive Biosystems, Inc., USA

### **Engineered Microprotein Ligands for Large Scale Biotherapeutic Purification**

John MacLennan, Edward Cohen, Rachel Kent, Arthur Ley, William Markland, Daniel Potter and Thomas Ransohoff, Dyax Corp., USA

### **Affinity Binding of Vampire Bat Plasminogen Activator to Pharmacia SEC Resins**

Michael McCaman, Carrie Souders and Erno Pungor, Jr., Berlex Biosciences, USA

### **Sodium Hypochlorite as an Alternative Sanitation Agent for Chromatographic Resins**

J. Kevin O'Donnell, Jon Fisher, Sheila Iuliano, Benita Lewis and Rob Rosen, TosoHaas, USA

### **Ceramic Hydroxapatite - A New Dimension in Chromatography of Biological Molecules**

Russ Frost and Peter Tunon, Bio-Rad Laboratories, Pete Gagnon, Validated Biosystems, Inc., USA, and Tetsuro Ogawa, Asahi Optical Co., Ltd., Japan

### **High Quality Purification of Bioactive Proteins by Use of Anti-Peptide Antibodies**

Shigeo Katoh, Masaaki Terashima and Kohei Miyaoku, Kyoto University, Japan

### **Mass Transfer Limitations In Protein Separations Using Ion Exchange Membranes Having Large Pores**

Mark R. Etzel and Frank T. Sarfert, University of Wisconsin, USA

## **Chromatography (Biochemical Engineering)**

### **Affinity Purification of Plasmids**

Thomas Schlupe and Charles L. Cooney, Massachusetts Institute of Technology, USA

### **Plasmid DNA Purification: Characterication and Use of a New Rigid Composite Ion Exchange Media**

Jonathan Coffman, Joyce Eldering and Alex Schwarz, BioSeptra, Inc., USA

### **Cone Chromatographic Column and Column Distribution by Mixing**

Mark Truei, Hatch Associates Ltd., USA

### **Preparative Gradient Elution Chromatography: A Case Study on Chemotactic Peptides**

Ajoy Velayudhan and Billy Kim, Oregon State University, USA

### **Anion-Exchange Adsorption of Proteins**

Richard Willson, University of Houston, USA

**Prediction of Breakthrough Curves in Ion Exchange Chromatography of Proteins**

Ulrik Borgbjerg and Jörgen Mollemp, Technical University of Denmark, Shuichi Yamamoto, Yamaguchi University, Japan, Oliver Kaltenbrunner and Alois Jungbauer, University of Agriculture, Austria

**Rational Stationary-Phase Selection and Design for Protein Ion-Exchange Separations**

A. Lenhoff and P. D. de Phillips, University of Delaware, and, Merck & Co., USA

**Chromatography (Applications/Validation)**

**Large Scale Protein A Affinity Chromatography of Immunoadhesins**

Steven M. Chamow, David H. Peers, Gregory S. Blank and Robert D. Hershberg, Genentech, Inc., USA

**Peptide Affinity Purification of Fibrinogen**

Chris Dadd, Joseph A Buettner, Scot R. Shepard, George A. Baumbach and David J. Hammond, Bayer Corporation, Ping Y. Huang and Ruben G. Carbonell, North Carolina State University, USA

**Protein A Affinity Chromatography Optimization Using Chaotropic Reagents**

David Jen and Russel T. Kawahata, Systemix Inc., USA

**Capture of Monoclonal Antibodies from Hybridoma Cell Culture Supernatant**

Alex Schwarz, Jonathan Coffman and Nicolas Voute, BioSeptra, Inc., and Patrick Gearing, Protein Design Labs, USA

**Experimental Design for Validation of Chromatographic Process Limits for Biopharmaceutical Manufacturing**

Brian R. Hubbard, Brian Kelly, Duane Bonam, Cathy Briasco Bonnie Germain, Pricilla Jennings, Jeff Robinson, Lei Shi, Jenifer Thomas, Richard Wright, Genetics Institute, USA

**Process Purification of Polypeptides by Reversed-Phase HPLC: Myth or Reality?**

C. David Carr, Paul Kostel and Philip Lu, The Separations Group, USA

**Preparative HPLC - Applications in the Pharmaceutical Industry**

Sam Guhan and R. Mark Guinn, Pfizer Inc., USA

**Simulated Moving Bed Technology - Possible Applications in Pharmaceutical Separations.**

R. Mark Guinn and Sam Guhan, Pfizer Inc., USA

**Simulated Moving Bed Chromatography, An Efficient Method of Separating Biological Compounds**

Roger-Marc Nicoud, Novasep, France

**Electrophoretic Separations**

**Continuous Separation of Protein By Recycling Free-Flow Isoelectric Focusing with Crude Feed Supply and Purified Product Removal**

Toshikuni Yonemoto and Ritsuko Ohtani, Tohoku University, and Akio Kitakawa, Miyagi National College of Technology, Japan

**A Prototype Electrochemical Chromatography Apparatus for Bioseparations**

Todd M. Przybycien, Philippe Lam and Kartik Kumar, Rensselaer Polytechnic Institute, USA

**Recovery and Purification of Glutamate by Electrodialysis from Fermentation Broth**

Tetsuya Kawakita, Ajinomoto Co. Inc., Japan

**Isoelectric focusing in Multicompartment Electrolyzer of a Recombinant Hirudin Variant HM2 from *Hirudinaria Manillensis*. Characterization of Minor Degraded Derivatives**

Pier Giorgio Righetti and A. Bossi, University of Milano, C. Visco, M. Mauriello, B. Valsasina and G. Orsini, Pharmacia & Upjohn, Italy, and E. Wenisch, University of Vienna, Austria

**Ultrafiltration**

**Ultrafiltration Process Control at the Molecular Level**

Robert van Reis, Elizabeth M. Goodrich, Christine L. Yson, Leah N. Frautschy and Rick Whiteley, Genentech, Inc., and Andrew L Zydney, University of Delaware, USA

**Overcoming the Rejection of Small Solutes by a Production Ultrafiltration Membrane**

Thomas Belval, Charles Kang and Jan Maes, Somatogen, Inc. USA

**Processes**

**Large-Scale Purification of Recombinant Streptavidin**

Roger J. Hinton, Chris Goward and Garry B. Stevens, Centre for Applied Microbiology Research, UK

**Purification of Recombinant Human Hemoglobin - A Case Study**

James R. Ryland, J. Jeffrey Plomer, Maura A. Matthews and Erin M. Palmer, Somatogen, Inc., USA

**Large-Scale Purification of a Neurotrophic Factor from Closely Related Isoforms and Host Proteins**

Somesh Nigam, P. Inampudi, G. Ruezinsky, J. Dugger and R. Rupp, Regeneron Pharmaceuticals, USA

**Metal Affinity Chromatographic Immobilization of Denatured Baculovirus Produced Fusion Proteins for Sequestered Purification, Modification and Refolding**

William G. Whitford, Blanca C. Csirke and Glenn P. Godwin, Life Technologies Inc., USA

**Protein Isolation from Transgenic Plants**

**Recovery of Recombinant Beta-Glucuronidase from Transgenic Corn**

Zivko Nikolov, Roque Evangelista, Ann Kusnadi, Iowa State University, Derrick R. Witcher, Elizabeth E. Hood and John A Howard, Pioneer Hi-Bred International, Inc., USA

**Development of Extraction and Purification Processes for Proteins Expressed in Transgenic Plants**

Vikram Paradkar, Brad Garcia and David Russel, Agracet Inc., USA

## **Protein Folding**

### ***Protein Refolding at High Concentration Using Size Exclusion Chromatography***

*Julian B. Chaudhuri and Boris Batas, University of Bath, UK*

### ***Protein Refolding Systems Using Molecular Chaperons***

*Akihiko Kondo and Hideki Fukuda, Kobe University, Japan*

### ***Heat Shock Proteins, Mediated Extractive Refolding Processes of Proteins Using Aqueous Two-Phase Systems***

*Ryoichi Kuboi and Isao Komazawa, Osaka University, Japan*

### ***Cyclodextrins as Protein Folding Aids***

*Nadarajah Karuppiah, L. Sharma and A Sharma, Central Michigan University, USA*

## **Process Analysis and Quality Control**

### ***Process Monitoring of a Trisulphide Derivative of Biosynthetic Derivative of Human Growth Hormone Produced in Escherichia coli***

*Jesper Christiansen and Benny Welinder, Novo Nordisk A/S, Denmark*

### ***Control of the Recombinant Factor VIIa Autolysis Reactions during the Purification Process***

*Jesper Christensen, Tony Jørgensen and Inger Møllerup, Novo Nordisk A/S, Denmark*

### ***Effect of Cell Culture Media Composition on Monoclonal Antibody Glycosylation Site Occupancy***

*Christopher Hill, S. Flatman, A. Sykes, A. Westlake and C. Wrigley-Jones, Lonza Biologics, and E. Parton, Celltech Therapeutics, UK*

### ***The Influence of hGH Sample Treatment on hGH Aggregation***

*Finn Matthiesen, Novo Nordisk A/S, Denmark*

### ***One Dimensional Tryptic Mapping as a Sensitive Method to Differentiate Two Monoclonal Antibody Preparations***

*Hema Sista, Mick Price and Russ Kawahata, Systemix Inc. USA*

