RECOVERY OF BIOLOGICAL PRODUCTS XII

THE WIGWAM RESORT
LITCHFIELD PARK, ARIZONA, USA

2-7 APRIL 2006

An International Conference

Sponsored by
The American Chemical Society
Division of Biochemical Technology

Conference Management Provided by:

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Conference Chairs

Brian Kelley, Wyeth BioPharma, USA
Inger Mollerup, Novo Nordisk A/S, Denmark
Jörg Thömmes, Biogen Idec, USA

Oral Session Chairs

E. Morrey Atkinson, Eli Lilly and Company, United States
Gregory Blank, Genentech, Inc., United States
Stuart Builder, Strategic BioDevelopment, United States
Ruben Carbonell, North Carolina State University, United States
Jonathan Coffman, Wyeth BioPharma, United States
John Curling, John Curling Consulting AB, Sweden
Mark Etzel, University of Wisconsin, United States
Conan Fee, University of Canterbury, New Zealand
Erik Fernandez, University of Virginia, United States
Shishir Gadam, Merck & Co., Inc., United States
Charles Glatz, Iowa State University, United States
Sam Guhan, Amgen, United States
Milton T. W. Hearn, Monash University, Australia
Abraham Lenhoff, University of Delaware, United States
Duncan Low, Amgen, United States
Christopher Lowe, University of Cambridge, United Kingdom
Andrew Lyddiatt, Millipore, United Kingdom
Rhona O'Leary, Genentech, Inc., United States
Todd Przybycien, Carnegie Mellon University, United States
Andy Ramelmeier, Global Biologics Supply Chain (GBSC), a J&J company, United States
Emily Shacter, Food and Drug Administration, United States
Abhinav Shukla, Amgen, United States
Arne Staby, Novo Nordisk A/S, Denmark
Richard Willson, University of Houston, United States

Poster Session Chairs

Charles Haynes, University of British Columbia, Canada
Maria-Regina Kula, Heinrich Heine University Dusseldorf, Germany
Anton Middelberg, University of Queensland, Australia

Workshop Chairs

Daniel Couto, Nuvelo, Inc, United States
Steve Cramer, Rensselaer Polytechnic Institute, United States
Alois Jungbauer, University of Natural Resources, Austria
Karol M. Lacki, GE Healthcare Biosciences, Sweden
Jill Myers, BioPro Consulting, United States
Nigel Titchener-Hooker, University College London, United Kingdom
L. A. M. van der Wielen, TU Delft, Netherlands
Ajoy Velayudhan, Centocor, United States

DAILY SCHEDULE

SUNDAY, 14 SEPTEMBER 2003

14:00-19:30
Wigwam Foyer
REGISTRATION / ACTIVITIES DESK OPEN

17:30-18:30
Wigwam Foyer
OPENING RECEPTION

18:30-19:30
Wigwam Ballroom
Welcome Remarks & Introduction to the Keynote Address
GLOBAL CHALLENGES FOR THE HIGH TECH, HIGH PRICE PHARMACEUTICAL INDUSTRY
Charlotte Erbsøll (NovoNordisk A/S, Denmark)

19:30-22:00
Sachem Hall
OPENING DINNER

MONDAY, 3 APRIL 2006

07:30-08:30
Sachem Hall
BREAKFAST

08:30-10:00
Wigwam Ballroom

IMPURITY REMOVAL, TARGETS & TESTING

Session Chairs: Duncan Low (Amgen, USA); Rhona O'Leary (Genentech, Inc., USA)

The United States Pharmacopoeia Protein A Reference Standard Project: Proposed Monographs and ELISA Collaborative Study Design
Michael Mulkerrin (Abgenix, Inc.)

Resolution of a Possible Potency Change during Development of a Late Stage Purification Process for a Monoclonal Antibody
Stephen Notarnicola (Biogen Idec)

A Regulatory Perspective on Control of Impurities
Steven Kozlowski (Food and Drug Administration)

10:00-10:30
Wigwam Foyer
BREAK WITH REFRESHMENTS

10:30-12:30
Wigwam Ballroom

D2 - DOWNSTREAM OF DOWNSTREAM

Session Chairs: Conan Fee (University of Waikato, New Zealand); Todd Przybycien (Carnegie Mellon University, USA)

Reactive Affinity Chromatography for the Purification and in Vitro Assembly of Virus-Like Particles
Daniel Lipin (University of Queensland)

PEGylation Cycling: A Technique for Maximizing Protein PEGylation Reaction Yields
Mark Chavez (Diosynth RTP, Inc.)

Transport and Partitioning of Pegylated Proteins in SEC and Ultrafiltration
Andrew Zydney (The Pennsylvania State University)

Evaluation of New Media for Neutral Polymer-Modified Biopharmaceuticals
James Van Alstine (GE Healthcare Biosciences)

12:30-13:30
Sachem Hall
LUNCHEON

13:30-17:30
Depart from Conference Centre Porte Cochere

- **TALIESIN TOUR**
- **WHITE TANK MOUNTAIN REGIONAL PARK - HIKING**

18:30-19:30
Sachem Hall
DINNER

19:30-21:30
Wigwam Ballroom

ASSESSING THE IMPACT OF MANUFACTURING PROCESS CHANGES ON PRODUCT COMPARABILITY AND IMMUNOGENICITY
Session Chairs: John Curling *(John Curling Consulting AB, Sweden);* Emily Shacter *(Food and Drug Administration, USA)*

Regulatory Perspectives on Assessing Comparability Throughout the Development/Commercial Life Cycle of Protein Products
Mary Sliwkowski (Genentech, Inc.)

Impact of Process Changes on Glycosylation in Monoclonal Antibodies
Amy Que (Pfizer, Inc.)

Immunogenicity: Assessing Risks and Developing Strategies
Daniela Verthelyi (Food and Drug Administration)

Physicochemical Characterisation of Biopharmaceuticals in a Regulatory Environment
Chris Jones (Natl Inst for Biological Standards and Control)

TUESDAY, 4 APRIL 2006

07:30-08:30
Sachem Hall
BREAKFAST

08:30-10:00
Wigwam Ballroom
THE DEVELOPMENT & REGULATORY INTERFACE: PROCESS VALIDATION
Session Chairs: Mark Etzel (University of Wisconsin, USA); Sam Guhan (Amgen, Inc., USA)

Considerations During Validation Of "Small Virus" (e.g. Parvovirus) Clearance Filters
Kurt Brorson (Federal Drug Administration)

TSE Clearance and a Quantitative TSE Risk Assessment for a Monoclonal Antibody Manufacturing Process
Peter Wojciechowski (Centocor)

Development of Fast Swab Methods for Use in Cleaning Verification.
Lars Sejergaard (Novo Nordisk A/S)

10:00-10:30
Wigwam Foyer
BREAK WITH REFRESHMENTS

10:30-12:30
Wigwam Ballroom
THE BIOREACTOR / PURIFICATION INTERFACE
Session Chairs: Charles Glatz (Iowa State University, USA); Andrew Lyddiatt (Millipore, United Kingdom)

Interaction between Upstream & Downstream Processing for the Production of HPV Virus Like Particles
Thomas Linden (Merck & Co., Inc.)

An Automated Microscale Platform for the Integrated Optimization of Fermentation and Microfiltration Operations
Nigel Jackson (University College London)

Approaches to Recovering Intracellular Enzymes from High Cell Density E. coli Fermentations
Jon Postlethwaite (Codexis Inc.)

Innocent Until Proven Guilty? Scale-Dependent Impact of Cell Culture on Recovery Performance
Lars Pampel (Amgen)

12:30-13:30
Sachem Hall
LUNCHEON

13:30-17:30
Depart from Conference Centre Porte Cochere

- **DESERT BOTANICAL GARDENS TOUR**
- **WHITE TANK MOUNTAIN REGIONAL PARK HIKING**

18:30-19:30
Sachem Hall
DINNER

19:30-21:30
Wigwam Ballroom
STRATEGIES FOR DEALING WITH INTELLECTUAL PROPERTY
Session Chairs*:* Milton W. Hearn (*Monash University, Australia); Arne Staby (Novo Nordisk A/S, Denmark)*

The Scope and Value of Process-related Intellectual Property
Janet McNicholas (McAndrews, Held & Malloy, Ltd)

Understanding the Patent Process – View from the USPTO Side
George Elliott (U.S. Patent & Trade Office)

Challenges and Opportunities in IP Management – An Asia Pacific Perspective
Tina Rankovic (Monash Commercial Pty Ltd)

Legal Requirements for Patentability
Anne Secher (Novo Nordisk A/S)

WEDNESDAY, 5 APRIL 2006

07:30-08:30
Sachem Hall
BREAKFAST

08:30-10:00
Wigwam Ballroom

SPEED TO CLINIC: PROCESS & TECHNOLOGY PLATFORM
Session Chairs: E. Morrey Atkinson (Eli Lilly and Company, USA); Richard Willson (University of Houston, USA)

Describing Monoclonal Antibody Interaction with Ceramic Hydroxyapatite: A High-Throughput Investigation of 15 Therapeutic Antibodies
David Wensel (Wyeth BioPharma)

Speeding up Bioseparation Process Design
Marcel Ottens (Delft University of Technology)

A Rapid Mapping of the Performances of Purification Processes to Speed-Up Process Development
Henri Kornmann (SERONO)

10:00-10:30
Wigwam Foyer
BREAK WITH REFRESHMENTS

10:30-12:30
Wigwam Ballroom

INDUSTRIAL CASE STUDIES: CLINICAL & COMMERCIAL PRODUCTION
Session Chairs: Gregory Blank (Genentech, Inc., USA); Shishir Gadam (Merck & Co., Inc., USA)

Strategies for Rapid Scale-up from Bench to Clinical Manufacturing: Case Study of a MAb
David Roush (Merck & Co., Inc.)

Three-Column Purification Process for Therapeutic Molecules Secreted in Pichia Pastoris Fermentations
Alan Klotz (Eli Lilly and Company)

What to Do When the Platform Fails…The Science-Based Development of an HSA/GLP-1 Fusion
Jason Bock (Human Genome Sciences, Inc.)

Case Study: Utilisation of Process Scale-Down Models for Process Performance Prediction and Experience of Actual Process Performance
Richard Francis (Protherics)

12:30-13:30
East Pool Patio
LUNCHEON

14:00-16:00
WORKSHOPS

Sachem West

ADVANCES IN MODELING OF SEPARATIONS

Session Chairs: Steve Cramer (Rensselaer Polytechnic Institute, USA); Karol Lacki (GE Healthcare, Sweden)

Evaluating the Performance of Expanded Bed Adsorption Columns
Tim Hobley (Technical University Denmark)

The pH Shift In Resin Pores During Protein Ion Exchange
Cornelius Ivory (Washington State University)

Mass-transfer Properties Of Plasmids And Nanoparticles On Monoliths And Chromatography Particles With Giga Pores
Alois Jungbauer (University of Natural Resources)

Examination of Protein-Ligand Interactions in Adsorptive Separations via Surface Plasmon Resonance
Mark Etzel (University of Wisconsin)

Modeling and Scale-Up of Column Packing-Comparison of Theoretical and Empirical Approaches
Justin McCue (Biogen Idec)

Arizona

DATA MINING & ANALYSIS

Session Chairs: Nigel Titchener-Hooker (University College London, United Kingdom); Ajoy Velayudhan (Bristol-Myers Squibb Company, USA)

Data Analysis and Exploitation in Bioprocess Downstream Processing
Gary Montague (University of Newcastle)

Lessons Learned from Development of a Custom Manufacturing Data Analysis Solution
Jeff Davis (Genentech, Inc.)

Data Clustering for Prediction of Downstream Process Routes
Chris O'Malley (University of Newcastle)

Application of Partial Least Squares to Sparse Data Sets for Design and Optimisation of Chromatographic Separations
Simon Edwards-Parton (Avecia Biotechnology)

Palo Verde

LEARNING FROM THE COMMODITIES INDUSTRY

Session Chairs: Daniel Couto (Nuvelo, Inc., USA); Luuk A. M. van der Wielen (TU Delft, Netherlands)

EBA Cascade Capture for Industrial Scale Protein Isolation: A Case Story on the Largest EBA Installation Commissioned to Date
Rob Noel (UpFront Chromatography A/S)

Integration of Fermentation and Downstream Processing for the Manufacturing of L-Phenylalanine
Emile van de Sandt (DSM)

Difficult Solid-Liquid Separations Made Easy?
Owen R.T. Thomas (University of Birmingham UK)

A New Format for Primary Capture – A High Throughput Alternative to Column Chromatography
Jerald Rasmussen (3M)

Wigwam Ballroom

NEW STATIONARY PHASES

Session Chairs: Alois Jungbauer (University of Natural Resources, Austria); Jill Myers (BioPro Consulting, USA)

Clustered-Charge Adsorbents, and Nucleic Acid Separations by Metal Affinity
Richard Willson (University of Houston)

Improvement of Selectivity in Highly Charged UF Membranes
Alex Xenopoulus (Millipore)

A New Cation Exchange Chromatography Resin with High Binding Capacity for Use in Protein Purifications
J. Kevin O'Donnell (Tosoh Bioscience LLC)

High Throughput Agarose Media
Anders Larsson (GE Healthcare)

Effects of Size of Biomacromolecular Structures on Chromatographic Adsorption and Transport
Abraham Lenhoff (University of Delaware)

18:00-19:00
Sachem Hall
DINNER

19:00-20:30
Aztec Ballroom
POSTER SESSION I

Session Chairs: Charles Haynes, (University of British Columbia, Canada); Maria-Regina Kula Heinrich (Heinrich Heine University, Germany); Anton Middelberg (University of Queensland, Australia)

Posters will be available for viewing throughout the conference. One-half of the authors will be present during the scheduled Poster Sessions. *(See page 93 for poster abstracts)*

#A1 Process Modelling and Simulation are Essential Decision Tools - Cohn and Chromatography Compared
John Curling (John Curling Consulting AB)

#A3 A Structured Decision Tool to Assess the Impact of Initial Capture Steps in the Production of Monoclonal Antibodies.
John Joseph (BioPharm Services, Inc.)

#A5 Effect of Conformational Changes of Biomolecules on Chromatographic Separations - Towards Structure-based chromatography design for proteins and other large biomolecules-
Shuichi Yamamoto (Yamaguchi University)

#B1 From Capture To Polish - Exploiting Structural Behaviour Of Nucleic Acids - Integrated Capture Process For Purification Of Plasmid DNA Based On Aqueous Two Phase Separation
Maria-Regina Kula (Heinrich Heine University Düsseldorf)

#B3 A Practical Strategy For Rotavirus-Like Particles Partial Purification From Insect Cell-Baculovirus Expression System
Marco Rito-Palomares (ITESM Biotechnology Center)

#B5 Bridging Platforms: A Single Primary Recovery Solution For Yeast and Mammalian Cell Culture
Bryan Dravis (Eli Lilly and Company)

#C1 Early Phase Choices And Late Phase Problems – A Fusion Protein Case Study
John Liddell (Avecia Biotechnology)

#C3 "Plug-and-Play" Purification – It's Not Just for Antibodies Anymore
Araba Lamouse-Smith (Human Genome Sciences, Inc.)

#C5 Elaboration of a Chemically Modified Octapeptide from a Recombinant Precursor
Thomas Furman (Eli Lilly and Company)

#D1 Intensification of Biopharmaceutical Processing
Anton Middelberg (University of Queensland)

#D3 Harvest Technology Transfer Considerations for the Relocation of a Commercial Manufacturing Process to a Different Facility
William Wang (Biogen Idec)

#D5 Challenges and Opportunities Beyond Monoclonal Antibodies - CTLA4Ig - A Case Study
Steven Lee (Bristol-Myers Squibb Company)

#E1 Large-Scale Pool-less Purification
Joseph Shultz (Amgen)

#E5 Removal Of Inactive Enzyme Monomer By Using Recirculation SEC And A Surprisingly Simple Peak Fractionation Procedure
Norbert Palma (Sandoz AG)

#F1 Using Gradient Chromatography Experiments to Predict Contaminant Clearance While Speeding Purification Development
Robert Gronke (Biogen Idec)

#F3 An Integrated Platform For Robust Virus And Contaminant Removal In Biomanufacturing
Uwe Gottschalk (Sartorius)

#F5 Viresolve NFP Filtration Development For A 150kd Protein: Characterization Of The Fouling Species And Use Of A Novel Virus Prefilter
Lee Madrid (Millipore)

#G1 Characterization of Reversed-Phase Adsorbents for Preparative Chromatography
Bjarne Rønfeldt Nielsen (Novo Nordisk A/S)

#G3 Optimization Of An Anion Exchange Chromatography Step For Monoclonal Antibody Purification
Suresh Vunnum (Wyeth BioPharma)

#G5 Resolution Of Heterogeneous Pegylated Proteins By Reversed Phase Chromatography
Todd Przybycien (Carnegie Mellon University)

#H1 Membrane Cascades for Protein Purification
Edwin N Lightfoot (University of Wisconsin)

#H3 Clarification of Cell Culture Harvest Utilizing Membrane Chromatography
Joseph Lepore (Centocor)

#H5 Investigations into the Properties and Function of Cellulosic Depth Filters for Clarification of Mammalian Cell Cultures
David Yavorsky (Millipore)

#J1 Loading, Mobile, and Stationary Phase Effects On Stability And Adsorption Of Marginally Stable Proteins During HIC
Erik Fernandez (University of Virginia)

#J3 Effect Of Dextran Based Surface Extenders On Binding And Elution Conditions During Ion Exchange Chromatography
Catharina Hemström Nilsson (GE Healthcare Biosciences)

#J5 Physiological Hydrophobic Interaction Chromatography. A New Technique for Process Applications
Peter Levison (Pall Life Sciences)

#K1 A Novel System for Rapid, Automated, High Precision Immunoassays and Micro-Scale Separations in Biopharmaceutical Development and Production
Scott Fulton (BioSystem Development)

#K3 Monitoring of Downstream Process Performance with SELDI Mass Spectroscopy
Eugene Schaefer (Bristol-Myers Squibb Company)

#K5 Exploring The Effects Of Lobe Pumping On Albumin
Joseph Bertolini (CSL limited)

#L1 Hexamer Affinity Resins That Bind The Fc Region Of Human Immunoglobulin G
Ruben Carbonell (North Carolina State University)

#L3 Implementation of Novel Affinity Ligands for Biotherapeutic Purification
Pim Hermans (Biotechnology Application Centre)

#L5 Fast Development Of Affinity Ligands Using Encoded Bead Combinatorial Libraries
Ib Johannsen (VersaMatrix A/S)

#M1 Development of a Scaleable Protein Purification Process Using Crystallization
Timothy Matthews (Genentech, Inc.)

#M3 Flocculation Of Antibody-Producing Mammalian Cells With Precipitating Solutions Of Soluble Cations And Anions
Jonathan Coffman (Wyeth BioPharma)

#M5 Recent Advances In High Gradient Magnetic Fishing (Hgmf)
Matthias Franzreb (Forschungszentrum Karlsruhe)

20:30-22:00
AZTEC BALLROOM
POSTER SESSION II

Posters will be available for viewing throughout the conference. One-half of the authors will be present during the scheduled Poster Sessions. *(See page 93 for poster abstracts)*

#A2 A Study on the Optimization of Productivity and Process Economics of Protein A Column Chromatography
Michael Phillips (Millipore)

#A4 System and Materials Design in Bio-Processing – Complementing or Fighting Each Other?
Reinhard Ditz (Merck KGaA)

#B2 Process Development Of An Ad35-Based Malaria Vaccine
Miranda Weggeman (Crucell Holland BV)

#B4 Towards A Generic Conjugation Strategy For Monoclonal Antibodies And Cytotoxic Small Molecules
Richard Blackmore (Seattle Genetics, Inc)

#B6 Process Purification Of Antibodies and Fc-Fusion Proteins: Protein A And Beyond
Sanchayita Ghose (Amgen)

#C2 Process Development of a Protein Susceptible to Proteolytic and Chemical Modifications: The Balance between Speed and Knowledge
Peter Lambooy (Eli Lilly and Company)

#C4 The Interaction Of Modern Strain And Fermentation Development With The Design Of Downstream Processes
Andreas Karau (Degussa)

#C6 Integrated Generic Processes for The Recovery Of Active Enzymes From E. Coli Inclusion Bodies
Howard Chase (University of Cambridge)

#D2 Monoclonal Antibody Purification by Alternative Methods
Sundar Ramanan (Amgen)

#D4 Development of a Purification Process for a Phase I Protein: a Case Study
John Pieracci (Biogen Idec)

#D6 Production And Purification Of Human Growth Hormone In A Pseudomonas Fluorescens-Based Platform
Anant Patkar (The Dow Chemical Company)

#E2 Assessment of Production-Scale Protein Purification Column Packing through Transition Analysis
Wenshan Lee (Amgen)

#E4 Evaluation of 0.4 M Diameter Tangential-Flow Column for Expanded Bed Absorption (EBA).
Andrew Alaska (CuraGen)

#E6 Integrated Process for Mono-PEGylation and In-Vitro Refolding
E. K. Lee (Hanyang University)

#F2 Assessing the Impurity Clearance Capacity of an Improved Adalimumab Process with Challenge Studies
R. Michael Boychyn (Abbott Bioresearch Center)

#F4 A Novel Procedure for Validation of Adventitious Virus Removal from a Monoclonal Antibody Process
David Kahn (Human Genome Sciences, Inc.)

#F6 Recovery of West-Nile Virus (WNV) vaccine: Development of a purification and inactivation process of a BSL-3 class virus
Marcel de Vocht (Crucell Holland BV)

#G2 Multi-Modal Chromatography For Purification Of Monoclonal Antibodies
Hans Johansson (GE Healthcare Biosciences)

#G4 Boutique Chromatography - Custom Design of SEC and HIC Resins Using Computational and Combinatorial Strategies
Charles Haynes (University of British Columbia)

#G6 Safety Factors In Filtration System Sizing
Herbert Lutz (Millipore)

#H2 Ultrafilter Consistency for Biopharmaceutical Processes - State of the Art Design and Manufacturing Control
Gabriel Tkacik (Millipore)

#H4 Evaluation of a Disposable Q-Membrane Filter in the Purification of a Monoclonal Antibody
Siegfried Rieble (Bristol-Myers Squibb Company)

#H6 Scale-Up of Microfiltration Systems: Fouling Phenomena and Vmax Analysis
Chia-Chi Ho (University of Cincinnati)

#J2 Displacers and Spacers for Preparative Ion-Exchange Chromatography of Biomolecules Using Displacement Mode: Properties, Performance, Advantages and Limitations
Barry Haymore (SACHEM Inc)

#J4 Towards the Use of Reversed-Phase Chromatography at the Process Scale
Abigail Laurent (Carnegie Mellon University)

#J6 Case Study - The Effect of Protein Solubility on the Development of a Hydrophobic Interaction Chromatography Step for a Glycosylated Antibody-Fusion Protein
Ronald Bates (Bristol-Myers Squibb Company)

#K2 Understanding Chromatography – The Influence Of Fluorescent Labels And Their Localization On The Protein Surface On Chromatographic Behaviour
Jürgen Hubbuch (Research Center Jülich)

#K4 Screening Biorecognition With Piezoelectric Sensors
Guilherme Ferreira (University of Algarve)

#K6 StratoCaptureTM - Protein A – Novel Immunoglobulin Affinity Purification Technology with Transgenic Safflower Oilbody in a Continuous Process
Helen Yang (SemBioSys Genetics Inc.)

#L2 Design And Performance Of Affinity Adsobents In A Cascade Process To Recover Seven Therapeutic Proteins From Source Plasma
Christopher Bryant (ProMetic BioSciences (USA), Inc.

#L4 Evaluation of Chromatography Media for Dual Sourcing Using a Platform Technology
Tim Breece (Genentech, Inc.)

#L6 Properties Of Affinity Membranes For Igg Separation
Cristiana Boi (University of Bologna)

#M2 Concentrating And Washing Protein Precipitates Using A Centrifugal Fluidized Bed
Marc Bisschops (Univalid Bioprocessing)

#M4 Use Of Flocculants To Improve Cell Culture Harvest Clarification And Product Capture Steps
Manoj Menon (Genzyme Corporation)

#M6 Simple, Effective Bioseparations Using Self-Cleaving Purification Tags
David Wood (Princeton University)

THURSDAY, 6 APRIL 2006

07:30-08:30
Sachem Hall
BREAKFAST

08:30-10:00
Wigwam Ballroom
CASE STUDIES: LIFE CYCLE MANAGEMENT

Session Chairs: Stuart Builder (Strategic BioDevelopment, USA); Andy Ramelmeier (GBSC (J&J), USA)

Development and Implementation of a Second Generation Insulin Analogue Process
Henrik Valore (Novo Nordisk A/S)

High-Yielding Process Within and Beyond Existing Plant Capacity
Benedicte Lebreton (Genentech, Inc.)

Continuous Improvement of the Humira Downstream Process – A Necessary Step in Product Life Cycle
Mindy Wan (Abbott Laboratories)

10:00-10:30
Wigwam Foyer
BREAK WITH REFRESHMENTS

10:30-12:30
Wigwam Ballroom

SELF-ASSOCIATION & AGGREGATION
Session Chairs: Abraham Lenhoff (University of Delaware, USA); Abhinav Shukla (Amgen, USA)

Protein Aggregation: Conformational, Colloidal and Surface Contributions
Theodore Randolph (University of Colorado, Boulder)

Disassembly and Reassembly of Human Papillomavirus Virus-Like Particles
Michael Kosinski (Merck & Co., Inc.)

cGMP Manufacture of Merozoite Surface Protein-2 – An Aggregation-Prone Malaria Vaccine Candidate.
Graham Hobba (GroPep Ltd)

Protein Aggregation at Interfaces
Georges Belfort (Rensselaer Polytechnic Institute)

12:30-13:30
Sachem Hall
LUNCHEON

13:30-17:30
Depart from Conference Centre Porte Cochere

- **JEEP TOUR**
- **THE HEARD MUSEUM TOUR**
- **WHITE TANK MOUNTAIN REGIONAL PARK - HIKING**

18:30-19:30
Wigwam Foyer
CLOSING RECEPTION

19:30-22:30
Sachem Hall
CLOSING BANQUET

FRIDAY, 7 APRIL 2006

07:30-08:30
Sachem Hall
BREAKFAST

08:30-10:00
Wigwam Ballroom

DESIGNING SEPARATIONS BASED ON FUNDAMENTAL STRUCTURAL OR SEQUENCE INFORMATION
Session Chairs: Ruben Carbonell (North Carolina State University, USA); Christopher Lowe (University of Cambridge, United Kingdom)

A Priori Prediction of Protein Affinity and Displacer Selectivity in Chromatographic Systems Using State-Of-The-Art Structure-Property Multi-Scale Modeling Techniques
Steve Cramer (Rensselaer Polytechnic Institute)

Hierarchical Partial Least Squares for Estimation of QSPR Models Including Interaction Effects for Prediction in Preparative Ion Exchange Chromatography of Proteins
Gunnar Malmquist (GE Healthcare)

A Combined Proteomics and Combinatorial Approach to Utilizing Impurity Profiles to Direct Process Development for Complex Biological Products
Timothy Hayes (American Red Cross)

10:00-10:30
WIGWAM FOYER
BREAK WITH REFRESHMENTS

10:30-12:30
Wigwam Ballroom

CHROMATOGRAPHY & BEYOND
Session Chairs: Jonathan Coffman (Wyeth BioPharma, USA); Erik Fernandez (University of Virginia, USA)

Capturing the Full Potential of Immobilised Metal Ion Affinity Chromatography with Recombinant Proteins
Milton T W Hearn (Monash University)

Development of Captureselect® Single-Chain Llama Antibody Fragments as a Platform Technology for Protein Purification
Mark Snyder (Bayer Corp.)

Rational Methods for Predicting Human Monoclonal Antibodies Retention in Protein A Affinity Chromatography and Cation Exchange Chromatography
Takashi Ishihara (Kirin Brewery Co., Ltd. Pharmaceutical Division)

Future Trends in Bioseparations
Robert van Reis (Genentech, Inc.)

12:30-14:00
Sachem Hall
CLOSING LUNCHEON