| Tuesday, March 10  |   |   |
|--------------------|---|---|
| 8:00AM-10:00AM     | Session 1: Setting the Conference Context and Drivers   |   |
|                    | Chair: Bob Adamson (Wyeth)  |   |
|                    | Keynote by Rob Garnick (Lone Mountain Biotechnology)<br>Keynote by Janice Reichert (Tufts University)     | Recent Developments in Biosimilars Development Trends for Biotherapeutics   |
|                    | Reynole by Sance Reichert (Turis Oniversity)  |   |
| 0:30AM-12:30PM     | Session 2: Emerging, "Disruptive" Technologies: Disruptive Scier  |   |
|                    | Chairs: Gordon Moore (Centocor), Brian Kelley (Genentech) and J   | im Swartz (Standford)<br>Glycoengineered Yeast: A Versatile Glycoprotein Expression Platform  |
|                    | Stefan Wildt (Merck)<br>Annie De Groot (Epivax)   | Giycoengineered Yeast: A Versatile Giycoprotein Expression Platform<br>Immunology Models  |
|                    | Bill Warren (Vaxdesign)   | In Vitro Biomimetic Human Immune System Models for Drug Assessment: MIMIC System  |
|                    | Karyn O'Neil (Cyntrix)  | Centyrin Alternative Scaffolds: A New Biotherapeutic Platform for J&J   |
| ::00PM-4:30PM      | Consign 2) Cutting Edge Applytical Techniques   |   |
| .00110-4.30110     | Session 3: Cutting-Edge Analytical Techniques<br>Chairs: Rohin Mhatre (BiogenIdec) and Tom Porter (Wyeth) |   |
|                    | Tom Laue (University of New Hampshire)  | Advances in Analytical Ultracentrifugation and Analytical Electrophoresis   |
|                    | Kermit K. Murray (Louisiana State University)<br>Igor Kaltashov (University of Massachusetts, Amherst)    | Coupling Microfluidic Chips to MALDI Mass Spectrometry<br>Mass Spectrometry-Based Strategies to Study Protein Architecture, Dynamics, and Binding   |
|                    | Steve Cohen (Waters Corp.)  | Chromatographic Analysis for Biopharmaceuticals: Current Trends and Future Prospects  |
|                    | Judy Chou (Genentech)   | High Throughput Analytical Methods for Bioprocess Development   |
| :30-6:00PM         | Poster Session  |   |
|                    | Chair: Louanne Hann (Wyeth)   |   |
| Vednesday, March ' | 11  |   |
| B:00AM-10:00AM     | Session 4: Accelerated Cell Culture Process Development   |   |
|                    | Chairs: Timothy Charlebois (Wyeth) and Rohini Deshpande (Amg  |   |
|                    | Florian Wurm (ETH-Zurich)   | Transient Expression in CHO Cells   |
|                    | Greg Hiller (Wyeth)   | Cell Culture Yield Improvements: Integrated Technologies Resulting in Leaps in Productivity   |
|                    | Luhong He (Lilly)   | Quantitative Analysis of Transfected MoAb Genes in Recombinant Single Cells and its Application in Cell Line Generation   |
|                    | Denny Kraichely (Centocor)  | Fluorescent Protein G Methylcellulose Screening A More Predictive Approach to Isolate High-Producing Candidate Manufacturing  |
| 0:30AM-12:30PM     | Session 5: Critical Quality Attributes, Specifications and Compara  | ibility   |
|                    | Chairs: Reed Harris (Genentech) and Paul Tsang (Amgen)  |   |
|                    | Sally Anliker (Lilly)   | Connecting CQAs to Control Strategies for Bioproducts   |
|                    | Patrick Swann (FDA)   | Regulatory Considerations for Evaluating Product Quality  |
|                    | Paul Motchnik (Genentech)   | Defining and Assigning CQAs   |
|                    | Izydor Apostol (Amgen)  | Analytical Perspective on Product Specification Lifecycle During Biotech Development  |
| 2:00PM-4:300PM     | Session 6: High Throughput Protein Formulation Development  |   |
|                    | Chairs: David Volkin (Centocor) and Bruce Kerwin (Amgen)  |   |
|                    | Juan Alvarez (TransForm Pharmaceuticals)<br>Russ Middaugh (University of Kansas, Department of Pharmacy)  | Application of High Throughput Technologies in the Development of Biopharmaceuticals<br>An Empirical Phase Diagram/High Throughput Screening Approach to the Formulation of Macromolecular Systems          |
|                    | Mark Manning (Legacy Biodesign)   | Efficient and Rationale Development of Liquid Formulations of Biopharmaceuticals  |
|                    | Byeong Chang (Symyx Technologies Inc)   | A Parallel, Microscale, Automated Approach to (Pre)Formulation and Stress Test Studies for Large Molecules  |
|                    | Albert Lee (Genentech)  | High Throughput Formulation Screening Using Rapid Stress Methods  |
| -20 C-00DM         | Pasta Ossian  |   |
| :30-6:00PM         | Poster Session<br>Chair: Louanne Hann (Wyeth)   |   |
|                    |   |   |
| :00-9:00PM         | Banquet   | Protein Anternation: Courses Consequences Control and Challenges  |
|                    | Keynote by John Carpenter (University of Colorado)  | Protein Aggregation: Causes, Consequences, Control and Challenges   |
| hursday, March 12  |   |   |
| :00AM-10:30AM      | Session 7: Emerging, "Disruptive" Technologies: Technology Op   |   |
|                    | Chairs: Gordon Moore (Centocor), Brian Kelley (Genentech), and a  |   |
|                    | Saddetin Ozturk (Centocor)<br>Brian Hubbard (Amgen)   | Facilities Based on Disposable Technology<br>Future Directions in Purification Technology   |
|                    | Brian Kelley (Genentech)  | Industrialization of mAb Processing: What Hath CHO Wrought  |
|                    | Tom Ransohoff (Bioprocess Consultants)  | Challenges of Introduction of New Technologies  |
|                    | 30-minute discussion  |   |
| 1:00AM-12:30PM     | Session 8: Functional Interaction Integration and Supergy in Dist   | form Development – from Amino Acid Sequence Identification to Protein Delivery  |
|                    | Chairs: Brendon Hughes (Wyeth) and Patricia Alred (Centocor)  |   |
|                    | Hubie Scoble (Wyeth)  | BioPharma Development Platform Concepts – What's Next?  |
|                    | Victor Fung (Amgen)   | Gaining Momentum From Platforms - How Other Functions Took a Good Idea and Made it Better   |
|                    | Pat Alred (Centocor)  | Applying QbD Principles as a Function of Product Maturity   |
| :00PM-4:30PM       | Session 9: Rapid and Economic Purification Process Developmer   | t   |
|                    | Chairs: Jorg Thommes (Biogen Idec) and Paul Mensah (Pfizer)   |   |
|                    | Sam Guhan (Amgen)   | How Not to Squander Cell Culture Titer Improvements During Downstream Processing  |
|                    | Lynn Conley (Biogen Idec)   | Using Partition Designs to Reduce Purification Process Characterization Time  |
|                    | Christopher J. Gallo (Wyeth BioPharma)  | Development of a Late Phase Off-Platform Manufacturing Process Within a Platform Development Timeline<br>The Use and Misuse of Rules-of-Thumbs for Rapid Development of Ion-Exchange Chromatography Process |
|                    | Tangir Ahamed (SynCo Bio Partners)<br>Karol Lacki (GE Healthcare)   | The Use and Misuse of Rules-of-Thumbs for Rapid Development of Ion-Exchange Chromatography Process<br>Development and Scale-Up of a Downstream Process for a Monoclonal Anti-Body: A Case Study             |
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