

Monday, March 19	
5:00 – 8:00 pm	Welcome Reception
Tuesday, March 20	
8:00 – 10:00	Session 1: Setting the Conference Context and Drivers Chair: Geoff Slaff (Amgen)
	Roger Perlmutter (Amgen) Conquering the Innovation Deficit in Drug Discovery Helen Winkle (CDER, FDA) Regulatory Modernization
10:00 – 10:30	Break Vendor and poster review
10:30 – 12:30	Session 2: Rapid Cell Line Development and Improved Expression System Development Chairs: Timothy Charlebois (Wyeth) and John Joly (Genentech)
	Amy Shen (Genentech) Stable Antibody Production Cell-Line Development with an Improved Selection Process and Accelerated Timeline Mark Leonard (Wyeth) High-Performing Cell-Line Development within a Rapid and Integrated Platform Process Control Pranhitha Reddy (Amgen) Applying Quality-by-Design to Cell Line Development Lin Zhang (Pfizer) Development of a Fully-Integrated Automated System for High-Throughput Screening and Selection of Single Cells Expressing Monoclonal Antibodies
12:30 – 2:00	Lunch Vendor and poster review
2:00 – 4:30	Session 3: High-Throughput Bulk Process Development Chairs: Brian Kelley (Wyeth) and Jorg Thommes (Biogen Idec)
	Colette Ranucci (Merck) Development of a Multi-Well Plate System for High-Throughput Process Development Min Zhang (SAFC Biosciences) CHO Media Library – an Efficient Platform for Rapid Development and Optimization of Cell Culture Media Supporting High Production of Pharmaceutical Proteins in Chinese Hamster Ovary Cells Nigel Titchener-Hooker (Univ. College London) The Use of Ultra-Scale-Down Approaches to Enable Rapid Investigation and Characterization of the Initial Downstream Process for Antibody Fragment Production in <i>E. Coli</i> Jon Coffman (Wyeth) High-Throughput Process Evaluation and Early-Stage Purification Process Development Ajoy Velayudhan (J&J/Centocor) High-Throughput and Automated Screening Methods to Facilitate Purification Process Development of Antibodies
4:30 – 7:30	Reception Vendor and poster review
Wednesday, March 21	
8:00 – 10:00	Session 4: Emerging, “Disruptive” Technologies Chairs: Duncan Low (Amgen) and Wei-Shou Hu (U. of Minnesota)
	James Swartz (Stanford) Cell-Free Protein Synthesis A.S. DeGroot (EpiVax) Epitope-Driven De-immunization of Protein Therapeutics Richard Tran (Univ, College London) Evaluation of New Manufacturing Paradigms for Downstream Processing David Wood (Princeton) Self-Associating Self-Cleaving Tags for Protein Purification
10:00 – 10:30	Break Vendor and poster review
10:30 – 12:30	Session 5: Technology Transfer: Case Studies and Business Practices Chairs: David Reifsnyder (Genentech) and Colette Ranucci (Merck)
	Hassan Madani (Amgen) Enbrel Process Modification and Transfer to Multiple Manufacturing Sites Post Market Launch Ray Arnold (Genentech) Improving Technology Transfer of Purification Process for Protein Pharmaceuticals Ellen McCormick (Pfizer) CP-675.206: Manufacturing Strategy Toward BLA/MAA

12:30 – 2:00	Xiaomi Tong (<i>Emergent Bio Solutions</i>) Lunch	Technology Transfer: From Research to Manufacturing for Biodefense Vaccine Products Vendor and poster review
2:00 – 4:30	Session 6: High-Throughput Analytical and Formulation Development Chairs: Rick Remmele (<i>Amgen</i>) and Peter DePhillips (<i>Merck</i>)	
4:30 – 6:30	Bing He (<i>Amgen</i>) Chris Roberts (<i>U of Delaware</i>) Peter DePhillips (<i>Merck</i>) James Broering (<i>Ga. Tech</i>) Mark Manning (<i>Legacy BioDesign</i>)	Automating Formulation Development Designing Stability Studies for Rapid Formulation Screening: Guidance from Fundamentals of Physical Protein Stability Accelerating Process Development: Automation of Analytical Assays Predicting Salt Effects on Protein Kinetic Stability: Implications for Accelerated Testing and Formulation of Protein-Based Pharmaceuticals Optimizing the Solution Behavior of Biopharmaceuticals: Rapid Determination of Osmotic second Virial Coefficients by Self-Interaction Chromatography
6:30-10:00	Anthony Lubiniecki <i>(Centocor R&D)</i>	Plenary Talk and Conference Banquet “Where is the Industry Likely to be Going, and How Much Acceleration is Too Much”
Thursday, March 22		
8:00 – 10:00	Session 7: Phase Specific Quality Systems and/or Standards and Analytical Comparability Studies Chairs: Reed Harris (<i>Genentech</i>) and Paul Tsang (<i>Amgen</i>)	
10:00 – 10:30	Thomas Porter (<i>Wyeth</i>) Drew Kelner (<i>Amgen</i>) Patrick Swann (<i>FDA</i>) Dieter Schmalzing (<i>Genentech</i>)	Assignment and Control of Product Isoforms Application of Quality by Design Principles to Biopharmaceutical Development Pre-Licensure Comparability Considerations Specification Setting for Biotechnology Products
10:30 – 12:30	Session 8: In-House Production or External Launch / Commercialization Facilities Chairs: David Robinson (<i>Merck</i>) and Eugene Schaefer (<i>Bristol-Myers Squibb</i>)	
12:30 – 2:00	Hubert Scoble (<i>Wyeth</i>) Wolfgang Berthold (<i>Biogen Idec</i>) Sunil Chhatre (<i>U. College London</i>) Eugene Schaefer (<i>BMS</i>)	History of Manufacturing Capacity Management at Wyeth Capacity Generation and Utilization at Biogen Idec Monte-Carlo Based Simulation Software for Evaluating Production Strategies in Commercial-Scale Pharmaceutical Operations Process Development Strategies to Support Multi-Site Manufacturing of Biologics
2:00 – 4:30	Session 9: Development Organization and Metrics Chairs: Maureen Halligan (<i>Amgen</i>) and David Chang (<i>Genentech</i>)	
4:30 – 4:45	Sue Steven (<i>Genentech</i>) Suzanne Jones (<i>Amgen</i>) Mary DiBiase (<i>Biogen Idec</i>) Hubert Scoble (<i>Wyeth</i>)	Biopharmaceutical Development : Think Like a Scientist, Behave Like a Business Using Portfolio Planning, Resource Modeling and Metrics Tools to Increase Speed to Development Development Speed and Efficiency: Matrix, Measure and Manage From Clone to Clinic: The Art and the Science of an Optimum Development Strategy
	Closing Comments Geoffrey Slaff (<i>Amgen</i>) and Chuck Goochee (<i>J&J/GBSC</i>)	