



**SBE's International Conference on  
Accelerating BioPharmaceutical Development**  
*Delivering Cost-Effective, Robust Processes and Methods  
Quickly and Efficiently*

**Technical Program**

**Monday, March 19**

- 2:00 - 5:00 pm Registration  
5:00 - 8:00 pm Welcome Reception (vendor and poster review)

**Tuesday, March 20**

7:00 - 8:00 am Breakfast (vendor and poster review)

8:00 - 10:00 am **S1 Setting the Conference Context and Drivers**

Chair: Geoff Slaff, Amgen

Speakers: Roger Perlmutter, VP R&D Amgen  
Helen Winkle, Director of the Office of Pharmaceutical Science, CDER

10:00am - 10:30 am Break (vendor and poster review)

10:30am - 12:30 pm **S2 Rapid Cell Line Development and Improved Expression System Development**

Session Chairs: Timothy Charlebois, Wyeth and John Joly, Genentech  
*Advances in expression systems and cell line development that address key drivers in the field: the need for rapid entry of new product candidates into the clinic and for highly efficient processes that maximize facility utilization and minimize costs of protein manufacture.*

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 Context

Pranhitha Reddy (Amgen) Applying Quality-by-Design into 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 pm Lunch (vendor and poster review)

2:00 - 4:30 pm **S3 High Throughput Bulk Process Development**

Session Chairs: Brian Kelley, Wyeth and Jorg Thommes, BiogenIdec  
*Applications of high throughput methodologies, including robotics, for medium optimization and purification process development.*

Colette Ranucci (Merck) Development of a Multi-well Plate System for High Throughput Process Development

Parviz Shamlou (Lilly) A Quality Risk Management Base for Miniaturization of Bioprocesses for Accelerating Biopharmaceutical Development

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 *e. Coli*

Jon Coffman (Wyeth) High Throughput Process Evaluation and Early-stage Purification Process Development

Ajoy Velayudhan (J&J/Centocor R&D) High-throughput and Automated Screening Methods to Facilitate Purification Process Development of Antibodies.

4:30 - 7:30 pm Reception (vendor and poster review)

**Wednesday, March 21**

7:00 - 8:00 am Breakfast (vendor and poster review)

8:00 - 10:00 am **S4 Emerging, "Disruptive" Technologies**

Session Chairs: Duncan Low, Amgen and Wei-Shou Hu, University of Minnesota  
*Technologies that could dramatically impact biopharmaceutical development over the next ten years.*

James Swartz (Stanford) Cell-free Protein Synthesis

A.S. De Groot (EpiVax) Epitope-Driven De-immunization of Protein Therapeutics

Richard Tran (U College London) Evaluation of New Manufacturing Paradigms for Downstream Processing

David Wood (Princeton) Self-Associating Self-Cleaving Tags for Protein Purification

10:00am - 10:30 am Break (vendor and poster review)

## Wednesday, March 21 Continued

- 10:30am - 12:30 pm **S5 Technology Transfer: Case Studies and Business Practices**  
Session Chairs: David Reifsnyder, Genentech and Colette Ranucci, Merck  
*The transfer of processes and assays into pilot plants and final manufacturing facilities.*
- 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
- Xiaomi Tong (Emergent BioSolutions) Technology Transfer: from Research to Manufacturing for Biodefense Vaccine Products
- 12:30 - 2:00 pm Lunch (vendor and poster review)
- 2:00 - 4:30 pm **S6 High Throughput Analytical and Formulation Development**  
Session Chairs: Rick Remmele, Amgen and Peter DePhillips, Merck  
*Applications of high throughput methodologies, including robotics, for analytical development and formulation development.*
- Bing He (Amgen) Automating Formulation Development
- Chris Roberts (U of Delaware) Designing Stability Studies for Rapid Formulation Screening: Guidance from Fundamentals of Physical Protein Stability
- Peter DePhillips (Merck) Accelerating Process Development: Automation of Analytical Assays
- James Broering (Ga. Tech.) Predicting Salt Effects on Protein Kinetic Stability: Implications for Accelerated testing and Formulation of Protein-Based Pharmaceuticals
- Mark Manning (Legacy BioDesign) Optimizing the Solution Behavior of Biopharmaceuticals: Rapid Determination of Osmotic Second Virial Coefficients by Self-Interaction Chromatography
- 4:00 - 6:30 pm Reception (vendor and poster review)
- 6:30 - 10:00 pm Plenary Talk and Conference Banquet  
Anthony Lubiniecki (Centocor R&D) "Where is the Industry Likely to be Going, and How Much Acceleration is Too Much"

## Thursday, March 22

- 7:00 - 8:00 am **S7 Phase-Specific Quality Systems and/or Standards and Analytical Comparability Studies**
- 8:00 - 10:00 am Session Chairs: Reed Harris, Genentech and Paul Tsang, Amgen  
*Product development strategies to meet phase-appropriate quality expectations*
- Thomas Porter (Wyeth) Assignment and Control of Product Isoforms
- Drew Kelner (Amgen) Application of Quality by Design Principles to Biopharmaceutical Development
- Patrick Swann (FDA) Pre-Licensure Comparability Considerations
- Dieter Schmalzing (Genentech) Specification Settings for Biotechnology Products
- 10:00am - 10:30 am Break (vendor and poster review)
- 10:30am - 12:30 pm **S8 Strategies for Production — In-house Production or External Launch / Commercialization Facilities**  
Session Chairs: David Robinson, Merck and Gene Schaeffer, Bristol-Myers Squibb
- Michael Kamarck (Wyeth) History of Manufacturing Capacity Management at Wyeth
- Gene Schaeffer (BMS) Process Development Strategies to Support Multi-Site Manufacturing of Biologics
- Michael Kowolenko (Biogen Idec) Manufacturing Capacity Planning at Biogen Idec
- Sunil Chhatre (Univ. College London) Monte-Carlo Based Simulation Software for Evaluating Production Strategies in Commercial-Scale Pharmaceutical Operations
- 12:30 - 2:00 pm Lunch (vendor and poster review)
- 2:00 - 4:30 pm **S9 Development Organization and Metrics**  
Session Chairs: Maureen Halligan, Amgen and David Chang, Genentech  
*Organizing for efficient discovery, development, and commercialization, and quantifying improvements in development speed and efficiency*
- Susan Steven (Genentech) BioPharmaceutical Development: Think Like a Scientist, Behave Like a Business
- Suzanne Jones (Amgen) Using Portfolio Planning, resource Modeling and Metrics Tools to Increase Speed to Development
- Bary DiBiase (Biogen Idec) Development Speed and Efficiency: Matrix, Measure, and Manage
- Hubert Scoble (Wyeth) Development Planning at Wyeth BioPharma
- 4:30 - 4:45pm Conference Closing Comments: G. Slaff, Amgen and Chuck Goochee, J&J/GBSC