

## Formulation Strategies for Protein Therapeutics

Held concurrent with IBC's BioProcess International Conference and Exposition  
September 21-23, 2010 – Rhode Island Convention Center – Providence, RI

**Registration is Now Available Online**  
[Register](#) by May 28<sup>th</sup> for the Lowest Rates  
or call 800.390.4078

### \*\*\* Preliminary Conference Agenda \*\*\*

*Note: Topics and speakers are subject to change. Agenda as of March 10, 2010*

**Tuesday, September 21, 2010**

#### Pre-Conference Workshop

**The Formulator of the Future; Using High Throughput Technologies, Informatics and Rational Design to Accelerate and Optimize Formulation Development**

- 7:45 *Registration and Networking Coffee*
- 8:25 **Chairperson's Opening Remarks**  
*David Volkin, Ph.D., Distinguished Professor, Pharmaceutical Chemistry, University of Kansas*
- 8:30 **Resolving Barriers to Developing High Throughput, Small Sample Volume Sample Preparation and Analytical Methods for Formulation Development**  
*Todd Gibson, Ph.D., Senior Research Scientist, Johnson & Johnson Global Manufacturing*
- 9:00 **Case Study: Data Management in Formulation Development; Effective Use of Multiple Complex Datasets in Solving Formulation Problems**  
*Haripada Maity, Ph.D., Senior Scientific Manager, Formulation Development, ImClone Systems*
- 9:30 **Case Study: Screening for Stability Characteristics in Early Stage Research**  
*Sharon Gao, Ph.D., Principal Scientist, Analytical Biochemistry, Biogen Idec, Inc.*
- 10:00 *Networking Refreshment Break*
- 10:30 **Case Study: Optimizing Informatics and Data Exchange with Contract Partners**  
*Pooja Arora, Ph.D., Research Investigator II, Bristol-Myers Squibb*
- 11:00 **Case Study: Rational Protein Design for Formulation Development**
- 11:30 **Panel Discussion: Use and Limitations of HTS in Formulation Development**
- Decision making with multiple datasets and advanced informatics
  - Experimental design for high throughput analytical methods
  - Representativeness to standard real-time and accelerated data
  - Challenges and technical gaps for formulation development
  - Implications for staff development and recruiting
- 12:15 *Workshop Ends; Lunch on Your Own*

#### **Main Conference – Day One**

- 1:10 **Chairperson's Opening Remarks**  
*Haripada Maity, Ph.D., Senior Scientific Manager, Formulation Development, ImClone Systems*
- 1:15 **Keynote Presentation: Holistic QbD: The Integration of Formulation, Process Development and Process Validation**  
*Sherry Martin Moe, Ph.D., Director, Late Stage Pharmaceutical and Processing Development, Genentech, Inc.*

## Comparability and Characterization Exercises during Formulation Development

- 2:00 **Comparability Strategy for Formulation and Dosage Form Development**
- 2:30 **Case Study: Characterization of Site Specific Degradation Pathways and Impact on Formulation Development**  
*Alexandra Lazar, Ph.D., Senior Scientist, Analytical and Pharmaceutical Sciences; ImmunoGen*
- 3:00 **Case Study: Change in Container Closure (Vial to Syringe) and the Stability Characterization Data Generated to Support the Change**  
*Angela Blake-Haskins, Ph.D., Senior Scientist, Drug Product Sciences, Human Genome Sciences, Inc.*
- 3:30 *Networking Refreshment Break*

## Tools for Development of Formulation and Drug Product Design Space

- 4:00 **Case Study: Formulation Aspects of Quality by Design Pilot Program for Biologics**
- 4:30 **Case Study: Design Space Development Based on Small Scale Models, Risk Assessment, DOE and Data Analysis**  
*Bingquan (Stuart) Wang, Ph.D., Senior Scientist, Pharmaceuticals, Genzyme Corporation*
- 5:00 **Technology Workshop**  
IBC's Technology Workshops offer supplier and service companies the opportunity to present product and service offers directly to the audience at the conference. For further information on sponsoring a Technology Workshop, please contact Jennifer McElligott at [jmcelligott@ibcusa.com](mailto:jmcelligott@ibcusa.com) or 508-614-1672 for additional information.
- 5:30 *Networking Cocktail Reception; Opening of BioProcess International Exhibit and Poster Hall*

## Main Conference – Day Two

**Wednesday, September 22, 2010**

- 7:30 *Networking Coffee*
- 7:55 **Chairperson's Opening Remarks**
- 8:00 **Keynote Presentation: FDA Perspective on Regulatory Filings and GMP Processes for Subvisible Particles in Protein Therapeutics**

## Implementing Analytical Methods and Control Steps for Subvisible Particles

- 8:45 **Data Driven Comparison of Detection and Characterization Technologies for Subvisible Particles: How do Existing Technologies Compare, and what is Needed?**  
*Brian Meyer, Ph.D., Research Fellow, Merck Research Laboratories*
- 9:15 **Case Study: Impacts of Container Closure and Primary Packaging on Subvisible Particles**
- 9:45 *Networking Refreshment Break in BioProcess International Exhibit and Poster Hall*
- 10:30 **Case Study: Investigation of Therapeutic Protein Particle Formation during Filling Operations**  
*Shona Patel, Ph.D., Merck Research Laboratories*
- 11:00 **Case Study: Linkage Between Stability-Aggregation Propensity-Particulate in the Development of Therapeutic Proteins**

11:30 **Analysis of Particles – Beyond Size**  
*Rajesh Krishnamurthy, Ph.D., Director, Analytical Group, Immunogen*

12:00 **Technology Workshop**  
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12:30 *Networking Luncheon in BioProcess International Exhibit and Poster Hall*

2:10 **Chairperson's Opening Remarks**  
*Andrea Ji, Ph.D., Scientist, Genentech, Inc.*

### Evaluation and Control of Biopharmaceutical Stability

2:15 **Case Study: Measurement and Mitigation of Oxidation in Therapeutic Proteins**  
*Andrea Ji, Ph.D., Scientist, Genentech, Inc.*

2:45 **Case Study: Formulation Development of Therapeutic Antibodies using High-throughput Fluorescence and Static Light Scattering Techniques: Role of Conformational and Colloidal Stability**  
*Sathish Hasige, Ph.D., Senior Scientist, Formulation Sciences, Process Biochemistry, MedImmune, Inc.*

3:15 **Case Study: The Impact of Prefilled Syringe Leachables on Protein Stability**  
*Xiaofeng Lu, Ph.D., Senior Scientist, Facet Biotech*

3:45 *Networking Refreshment Break in BioProcess International Exhibit and Poster Hall*

4:30 **Low Volume, High-Throughput Thermal Analysis of Proteins by Fluorescence Dye Binding using a RT-PCR Instrument**  
*Thomas Palm, Ph.D., Senior Research Investigator, Pharmaceuticals, Bristol Myers Squibb*

### Formulation Development for Lyophilized Products

5:00 **Case Study: Improving the Stability of Lyophilized Products**  
*Adora Padilla, Ph.D., Scientist, KBI Biopharma*

5:30 **Case Study**

6:00 *Networking Cocktail Reception in BioProcess International Exhibit and Poster Hall*

### Main Conference – Day Three

**Thursday, September 23, 2010**

7:30 **Best Practices Breakfast Roundtables: Company Responses to Subvisible Particle Challenges**

- What detection and characterization technologies are being used by other companies?
- Are there any clinical data suggesting there are correlation between SVP and immunogenicity?
- What are the strategies to address the SVP difference between different lots?
- What strategies are being used across the industry to respond to questions from the FDA about particle measurement and control?
- How is the elevated concern over subvisible particles impacting existing projects?
- How are others approaching particle content in terms of specification setting and risk management?

8:25 **Chairperson's Opening Remarks**

**Formulation Strategies for Vaccines**

8:45 **Case Study**

9:15 **Case Study: Developing and Correlating Accelerated Stability Studies for Vaccine Development**

*Manvi Hasija, Ph.D., Sanofi-Pasteur, Canada*

9:45 **Case Study: Formulation Development for an Adjuvant Vaccine**

10:15 *Networking Refreshment Break in Meeting Room*

**Formulation Impacts of Device and Packaging Systems**

10:45 **Characterization, Modelization and Control of Primary Packaging Surfaces to Minimize Non-Native Aggregation of Therapeutic Proteins**

*Thomas Ballet, R&D Engineer, Advanced Technology, Becton Dickinson Medical Pharmaceutical Systems*

11:15 **Case Study: Formulation Considerations in Development of a Device or Packaging System (materials, extractables/leachables, manufacturing, mechanical forces, storage conditions)**

11:45 **Case Study**

12:15 *Networking Luncheon, Last Chance for Exhibit and Poster Viewing*

1:55 **Chairperson's Opening Remarks**

**Formulation Development for Next Generation Biologics**

2:00 **Case Study: Formulation Development for Fusion Proteins**

2:30 **Case Study: Formulation Development for Antibody-Drug Conjugate**

*Shan Jiang, Ph.D., Seattle Genetics*

3:00 **Case Study: High Throughput Screening Method for Adenoviruses (Very Low Concentration Protein Complex)**

*Pieter Rijken, Ph.D., Scientist, Formulation & Comparability, Crucell, The Netherlands*

3:30 *Networking Refreshment Break*

3:45 **Case Study: Formulation Development for Subcutaneous Delivery of Plasma Derived Proteins**

*Sylvain Huille, Ph.D., Head of Department, Biopharmaceutical Development, LFB Biotechnologies, France*

4:15 **Case Study: Formulation Development for a Retacrit Biosimilar Epoetin**

4:45 *Conference Ends*