

Monday, December 8, 2008

Ambassador Ballroom

8:00 Registration and Coffee

9:00 Chairperson's Opening Remarks
James Weidner, Director, Process Engineering, Amgen Inc.

Keynote Presentations

- 9:15 **An Integrated Approach to Global Operations: Making Biotech Manufacturing and Operations Strategically Relevant in Today's Global Biotechnology Environment**
John Cox, Senior Vice President, Global Manufacturing, Biogen Idec
- 10:00 **Translation of Operational Excellence Methodologies from Theory to Action, Results and Sustainability**
Curran Simpson, Senior Vice President, Operations, Human Genome Sciences, Inc.

10:45 Exhibit and Poster Hall Opens with Networking Refreshment Break

Shared Session: Regulatory Updates,
Risk Management and Validation

- 11:15 **Risk Based Validation and Inspection Readiness**
Christa Hartmann, Ph.D., Director, Corporate Quality, Genentech, Inc.
- 11:45 **Practical Experience from Execution of Risk-Based Commissioning and Qualification**
Magnus Jahnsson, Head of Function QA/HSE, Pharmadule AB, Sweden; Former Scientific Administrator, Inspections Sector, EMEA
- 12:15 **Technology Workshop**
Microbiological Performance of Commercially Available Single-Use Connectors
Kerry Roche Lentine, Manager, Virology and Microbiological Sciences, Bioprocess Division, Millipore Corporation



12:45 Networking Luncheon and Poster/Exhibit Viewing

Disposables and Facilities

Ambassador Ballroom

Implementation of Disposable Technologies

- 2:00 Chairperson's Remarks
Kellen Mazzarella, Engineer I, Process Development Engineering, Genentech, Inc.
- 2:15 **Developing a Supplier Innovation Roadmap to Speed Development and Implementation of Disposables Technology**
Jennifer Maynard, Black Belt Operational Excellence, Bayer Healthcare
- 2:45 **Integration of HyClone Single-Use Bioreactors into the Process R&D Early Stage Network** **CASE STUDY**
Terrence Allotta, Engineer I, Process R&D, Genentech, Inc.
- 3:15 Networking Refreshment Break with Poster/Exhibit Viewing
- 3:45 **Update: 1,000L Disposable Bioreactor System Evaluation and Performance** **CASE STUDY**
Kelly R. Wiltberger, Manager, Cell Culture Development, Biogen Idec
- 4:15 **Use of Disposable Bag Technology in a Closed Upstream Biologics System** **CASE STUDY**
Glen Williams, Senior Vice President, Technical Operations, Biolex Therapeutics
- 4:45 **An Innovative Approach to the Use of Single-Use Products Based on Principles of Lean Process Improvement** **CASE STUDY**
Bryan Shingle, Manager, Clinical Material Services, Clinical Drug Substance Manufacturing, Centocor

Operational Excellence

Presidents III & IV

Applying Lean Principles for Cost Reduction

- 2:00 Chairperson's Remarks
Robert Bottome, Director, South San Francisco Production Operational Excellence, Genentech, Inc.
- 2:15 **Lean Plants of the Future – Application of Lean Tools to Biotech Production**
Robert Caren, Associate Director, Manufacturing Sciences and Technology, Genentech, Inc.
- 2:45 **Creating a Culture of Continuous Improvement** **CASE STUDY**
Dave Bain, Director, Industrial Engineering, Amgen
- 3:15 Networking Refreshment Break with Poster/Exhibit Viewing
- 3:45 **The Keys to Sustaining High Performance**
Shane Yount, Senior Partner, Competitive Solutions, Inc.
Tim Tousey, Manager of Operational Excellence, Zebulon Site, GlaxoSmithKline
- 4:30 **Reducing Costs while Improving Compliance** **CASE STUDY**
Chris S. Driscoll, Principal, Tunnell Consulting
- 4:45 **Leading Change in Pursuit of Operational Excellence** **CASE STUDY**
David Sadi, Associate Director, Operational Excellence, Biogen Idec

5:15 Networking Reception in Poster and Exhibit Hall Sponsored by IBC Life Sciences

6:15 Site Tour to Catalent Pharma Solutions

Buses depart the Washington Duke Inn & Golf Club at 6:15 pm and return at 9:45 pm. Refreshments will be served. Please sign up at IBC registration desk.

Disposables and Facilities

Ambassador Ballroom

Current Perspectives on Extractables and Leachables

- 8:45 **Chairperson's Remarks**
 Jerold Martin, M.Sc., *Senior Vice President, Pall Life Sciences; BPSA Director and Chair, Standards and Guidance Committee, Bio-Process Systems Alliance (BPSA)*
- 9:00 **Incorporating Industry Best Practices into Development of an Extractable/Leachable Program**
 Aditya Wakankar, Ph.D., *Associate Scientist, Pharmaceutical Development, Genentech, Inc.*
- 9:30 **Single-Use BioProcess Containers for Storage of a Biopharmaceutical Drug Substance** **CASE STUDY**
 Richard Strong, Ph.D., *Scientist II, Analytical Development, Biogen Idec*
- 10:00 **Development of Supplier-Generated Extractables Data for Integrated Single-Use Systems**
 Christopher J. Mach, *Global Product Manager, Allegro Single Use Systems, Pall Life Sciences*
- 10:30 *Networking Refreshment Break with Poster/Exhibit Viewing*
- 11:00 **Audience Interactive Panel Discussion**
 Moderator: Jerold Martin, *Pall Life Sciences*
 Panelists: Christopher J. Mach, *Pall Life Sciences*; Richard Strong, Ph.D., *Biogen Idec*; Aditya Wakankar, Ph.D., *Genentech, Inc.*
- 11:30 **Technology Workshop**
High Performance Disposable Capture Chromatography 
 Chris Shields, *Marketing Director, Natrix Separations, Inc.*
- 12:00 **Luncheon Presentation**
Allegro™ Flexible Solutions: An Overview of Pall Single Use Technologies, Systems and Capabilities  *Sponsored by Pall Life Sciences New Science. New Thinking.™*
 Christopher J. Mach, *Global Product and Marketing Manager, Allegro Single Use Systems*
- 12:45 *Coffee and Dessert in the Exhibit Hall*

Logistical Considerations

- 1:15 **Chairperson's Remarks**
 Melody Scott, *Process Engineer III, Biogen Idec*
- 1:30 **Production of Viral Products in a Multi-Product cGMP Environment**
 Roger Lias, Ph.D., *President, Eden Biodesign, Inc.*
- 2:00 **Developing Disposable Shipping Mechanisms: Overcoming Challenges Inherent in a Fragile System**
 Kellen Mazzarella, *Engineer I, Process Development Engineering, Genentech, Inc.*
- 2:30 **Reduce, Reuse, Recycle, and Then What? Converting Waste-to-Energy**
 To be Announced
- 3:00 **The Current Limitations on the Use of Disposables in Clinical Manufacturing**
 Joshua Froimson, *Associate Director, Site Support, Abbott Bioresearch Center*
- 3:30 *Networking Refreshment Break with Final Opportunity for Poster/Exhibit Viewing*

Enhancing Productivity, Flexibility and Economics of Biopharm Manufacturing Facilities and Operations

- 4:00 **Predicting Production Run Rates Using Realistic Process Models** **CASE STUDY**
 Carnley L. Norman, Ph.D., *Principal Engineer, Amgen*
- 4:30 **The Use of Simulation in the Design and Capacity Analysis of a Biotech Manufacturing Facility** **CASE STUDY**
 Richard G. Dargatz, P.E., *Engineering Consultant, Engineering Tech Center, Eli Lilly and Company*
- 5:00 **Disposable Perfusion Bioreactor Technology for Manufacturing Therapeutic Proteins**
 Gan Wei, Ph.D., *Director, Bioengineering, Shire Human Genetic Therapies*

Operational Excellence



Presidents III & IV

- 8:45 **Chairperson's Remarks**
 Siddharth J. Advant, Ph.D., *Principal & Head, West Coast Office, Tunnell Consulting*

Impact of Raw Materials on Cost Reduction

- 9:00 **Optimization of Resin and Membrane Use in Commercial Biopharmaceutical Manufacturing**
 Sourav K. Kundu, Ph.D., *Director, Process Development, Amgen*
- 9:30 **Shelf Life Extensions of Raw Materials, Resins and Disposable Components** **CASE STUDY**
 Freddie W. West, *Senior Scientist, Process Development, Amgen*

Design for Manufacturability

- 10:00 **Validation and Six Sigma**
 Robert Bottome, *Director, South San Francisco Production Operational Excellence, Genentech, Inc.*
- 10:30 *Networking Refreshment Break with Poster/Exhibit Viewing*
- 11:00 **Application of the Lean Diagnostic Process in a Biopharmaceutical API Plant** **CASE STUDY**
 Elizabeth Fabián, *Business Excellence Lean Program Manager, Global Pharmaceutical Operations, Abbott Laboratories*
- 11:30 **Technology Workshop (Ambassador Ballroom)**
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 Chris Shields, *Marketing Director, Natrix Separations, Inc.*
- 12:00 **Luncheon Presentation (Ambassador Ballroom)**
Allegro™ Flexible Solutions: An Overview of Pall Single Use Technologies, Systems and Capabilities  *Sponsored by Pall Life Sciences New Science. New Thinking.™*
 Christopher J. Mach, *Global Product and Marketing Manager, Allegro Single Use Systems*
- 12:45 *Coffee and Dessert in the Exhibit Hall*
- 1:15 **Optimizing the Use of a Multi-Product Biologics Clinical Manufacturing Facility** **CASE STUDY**
 Joseph K. McLaughlin, *Associate Research Fellow, Bioprocess R&D, Pfizer Inc*

Process Analysis for Production Efficiency

- 1:45 **Chairperson's Remarks**
 Joshua Froimson, *Associate Director, Site Support, Abbott Bioresearch Center*
- 2:00 **BioPharma's New Paradigm in Operational Excellence (OpEx): How New Process Design Tools Support the Goals of Quality by Design (QbD) and Process Analytical Technology (PAT)**
 William G. Whitford, *Senior Manager, Technical Development Collaborations, Thermo Fisher Scientific*
- 2:30 **Audience Interactive Panel Discussion**
Impact of Operational Excellence on the Design of Platform Processes and Facilities
 Moderator: Chris S. Driscoll, *Principal, Tunnell Consulting*
 Panelists: Robert Bottome, *Director, South San Francisco Production Operational Excellence, Genentech, Inc.*; Robert Caren, *Associate Director, Manufacturing Sciences and Technology, Genentech, Inc.*; Parrish Galliher, *Founder and Chief Technology Officer, Xcellerex, Inc.*; Sourav K. Kundu, Ph.D., *Director, Process Development, Amgen*; Gan Wei, Ph.D., *Director, Bioengineering, Shire Human Genetic Therapies*
- 3:30 *Networking Refreshment Break with Final Opportunity for Poster/Exhibit Viewing*
- 4:00 **Use of Multivariate Analysis and Quality by Design for a Late-Stage Bioprocess Validation** **CASE STUDY**
 NingNing Ma, Ph.D., *Senior Principal Scientist, Pfizer Inc*
- 4:30 **Improving Biomanufacturing Excellence Based on Process Analytical Technology (PAT) / Quality By Design**
 Glenn Restivo, *Life Sciences Specialist, Siemens*
- 5:00 **Using the Past to Design the Future: Using Empirical Data and Simulation Modeling in Process Design**
 Rick Johnston, *Co-Director, Center for Biopharmaceutical Operations, University of California, Berkeley*

Wednesday, December 10, 2008

Site Tour to Golden LEAF BTEC Facility: A World-First and World-Class Training Facility

Buses depart from the Washington Duke Inn & Golf Club at 8:00 am and return at approximately 12:30 pm, making a stop at Raleigh-Durham International Airport at approximately 11:45 am. Please sign up at IBC registration desk