

Biopharmaceutical Manufacturing and Development

IBC's 7th International
BMD
Summit

September 12-14, 2011
Doubletree Mission Valley
San Diego, CA

Achieving Speed and Savings in Today's Manufacturing Environment

Keynote Presentations

Deploying Business Process Excellence in Biologics Manufacturing



James R. Kasselmann
Director, Clinical
Manufacturing
Genentech, Inc.

Next Generation Process in a New Biotechnological Facility



Kim Sandell
Director, Operations
Management & Operational
Excellence, Pfizer, Sweden

*Facility of the Year Award:
Operational Excellence*

Amgen's Perspective on Manufacturing of the Future



Stephen J. Hill
Executive Director
Manufacturing Technology
Amgen

Free Access to Co-Located Event:

IBC's 8th Annual Early Development Forum

Preclinical Scale Bioprocessing

A Best Practices Exchange for R&D
to IND Stage Biologics Development

Enabling Flexible Facilities

Accommodate your changing product and process needs with:

- Alternatives to Protein A
- Risk-Based Decisions for Multi-Product Facilities
- Manufacturing Platforms Used for Biosimilars
- Large Scale Integration of Disposables
- Novel Downstream Technologies

Biomanufacturing Excellence

Ensure your products' quality, safety and competitiveness with:

- Continuous, Disposable Antibody Purification
- Process Adaptations for Increased Robustness and Risk Mitigation
- Strategies for the Development and Manufacturing of Biosimilars
- Supply Chain Risk Mitigation
- Risk Management Approaches to Process Design and Technology Transfer

In-Depth Symposium:

Assessing and Preventing the Risk of Using Disposables

- Managing Supplier Relationships including Raw Material Changes
- Process Validation for Extractables and Leachables

Bronze Sponsors:

Lonza



Life Sciences

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Ensure Quality, Safety, Competitiveness and an Uninterrupted Supply of Safe Products to Patients

Are you or your team responsible for ensuring the efficiency, supply chain security, consistency, safety, and uninterrupted supply of your company's product?

Do you need to ensure that your facility and processes are optimized to accommodate today's best technologies as well as tomorrow's products?

The **BMD Summit** brings you up-to-the-minute reports from industry leaders to answer your questions about ensuring facility flexibility and biomanufacturing excellence. Learn how to drive down costs, achieve more with fewer resources, develop efficient, flexible, multi-product facilities, use manufacturing capacity more efficiently, avoid raw material contamination, and reduce process variability with this one multidisciplinary event.

Plan now to attend the only event that focuses on implementation strategies that will help you plan for the integration of single-use technologies and other flexible manufacturing schemes. Take advantage of attending sessions from both of the tracks at this conference, as well as sessions of the co-located Preclinical Scale Bioprocessing conference.

Plan for Integration of New Technologies and Strategies:

Presentations will cover:

- Overall facility strategies from **Shire** and **BioMarin**, whose unique use of disposables break new ground in facility efficiency.
- **Percivia's** comparison of Protein A, Non-Protein A, and disposable downstream processes.
- Critical evaluations of an alternative polishing platform by **ImClone**, disposable clarification step by **Biogen Idec**, disposable depth filtration by **Pacific GMP**, and **Lonza's** integration of disposables in existing facilities for downstream purification of high titer processes.
- Strategies for developing multi-product facilities and incorporation of disposables from **ImClone**, **Hospira**, **Biogen Idec** and **Genentech**.
- **Merck's** continuous, disposable antibody purification process.
- Biosimilars development strategy from **Tanvex Biologics**.
- Supply chain risk mitigation, including strategies for sole sourcing from **UC Berkeley** and mitigating raw materials impact from **Amgen**.

Special Features

Keynotes and plenary presentations on two ISPE-awarded facilities of the year from Pfizer and Shire, Genentech's business process excellence strategy to receive "Class A" certification, and Amgen's perspective on future plans for more cost-effective manufacturing.

"Greatly facilitates keeping informed of current key biotech practices, learnings, and players/SMEs."

– Stacey M. Kaneshiro, Senior Consultant Engineer, Eli Lilly and Co.

"This will be a great opportunity to learn what other specialists are doing in the disposables for biotech arena."

– James W. Chrostowski, Ph.D., Engineer III, Biogen Idec

Plus Free Access to Co-Located Event:

IBC's 8th Annual Early Development Forum

Preclinical Scale Bioprocessing

A Best Practices Exchange for R&D to IND Stage Biologics Development

Industry companies are now working hard to structure their preclinical development programs to be efficient, cost-effective and fast, while meeting the IND requirements of regulatory agencies. To do this successfully requires an in-depth knowledge of products and processes, coupled with sound organizational and scientific strategies.

- **Takeda San Francisco** outlines the challenges of working multiple CMOs on the early development of a complex antibody-drug conjugate
- **Neogenix** assess the analytical comparability of two GMP lots of a therapeutic monoclonal antibody produced by two different
- **Centocor** discusses parallel processing and early development strategies that increase project success rates in preclinical
- **Abbott** describes the evolution of its preclinical/clinical cell culture platform from hydrolysate-based to chemically defined and how these changes impacted the project timeline
- **Biogen Idec** explores its strategies for streamlining cell line screening and selection in manufacturing processes
- **Allergan** shares its experience in the first time development of platformed analytical and process development approaches, and Immunogen breaks down the cost and time savings of an existing platform development
- **Merck** analyzes a comparative study of process performance and quality for small scale single use bioreactor systems
- **Human Genome Sciences** examines the challenges of fitting novel proteins into platformed downstream production processes

www.IBCLifeSciences.com/Preclinical

Assessing and Preventing the Risk of Using Disposables

7:30 *Coffee and Registration*

8:15 **Chairperson's Opening Remarks**

Ekta Mahajan, Senior Engineer, Genentech, Inc.

8:30 **Risk Mitigation Strategies for Disposable Materials**

This presentation will explore Risk Mitigation Strategies for single-use production systems and components. These strategies will focus on an enhanced supplier relationship model, quality and functional requirements as they relate to the process requirements, and the financial implications. Supplier owned safety stock inventories becomes more important as well as the ability of the supply industry to make their products interchangeable with other suppliers' products.

Leslie B. Cianella, Strategic Sourcing Manager, Procurement, Genentech, Inc.

9:00 **NEW UNPUBLISHED DATA CASE STUDY What to Do when There Is a Change to a Polymeric/Plastic, Raw-Material Based Product?**

Change notices provided by a supplier to an end-user will sometimes involve a raw material change of a key single use disposable item. Case studies will be discussed based on plastic material changes typically found with single use disposable products. The studies will describe how the changes were implemented and how they can be implemented more easily and faster for future projects.

Trishna Ray-Chaudhuri, Ph.D., Technical Consultant, Trishna LLC

9:30 **Applying QbD Principles to Manufacturing with Single Use Systems**

A QbD approach to Process Development offers significant advantages at commercialization. This presentation will outline the application of Risk Management, Quality by Design, and statistical process monitoring to the decision-making, implementation and qualification processes for single use manufacturing operations.

Robert Repetto, Director, External Affairs, BioTherapeutics Pharmaceutical Sciences, Pfizer

10:00 *Networking Refreshment Break*

10:30 **Risk Mitigation with Disposables**

Single-use technology offers big risk mitigation advantages over traditional bioprocessing platforms. Our industry is rapidly adopting disposable systems for the obvious quality benefits – minimizing cross contamination and reducing the impact of failure events. This presentation expands the focus to include not only the obvious, but also mitigation of other business-related risks with traditional approaches such as lost speed, process-dependency, and poor asset utilization.

Lisa Alexander, Vice President, Regulatory and Quality, Xcellerex, Inc.

11:00 **NEW UNPUBLISHED DATA CASE STUDY Process Development and Process Validation of Biotherapeutics Manufacturing Using Single-Use Systems**

To manufacture a sterile solution of a protein therapeutic product from plasma, disposable systems were implemented. The evaluation of extractables and leachables was performed as part of the process validation. The validation strategy included conducting a risk assessment, matrixing products, and selecting reasonable worst-case test conditions. The safety and quality impacts of extractables and leachables on protein products were assessed.

David M. Weber, Senior Manager, Process Development, R&D, CSL Behring
Weibing Ding, Ph.D., Senior Technical Manager, Scientific and Laboratory Services, Pall Life Sciences

Panel Discussion

11:30 **Industry/Supplier Panel Discussion: Risk Mitigation Strategies for Implementation of Disposables**

- Technical understanding of raw materials
- Impact of sterilization on disposables components
- Validation of supplier data
- Is use of disposables "just" a MOC change?
- Are we ready for commercial applications?
- Standardization of extractable and leachable studies across industry
- Gaps between supplier and end user requirements

Moderator:

Ekta Mahajan, Senior Engineer, Genentech, Inc.

Panelists:

Jeffrey Carter, Director of Research and Development, GE Healthcare

Leslie B. Cianella, Strategic Sourcing Manager, Procurement, Genentech, Inc.

Weibing Ding, Ph.D., Senior Technical Manager, Scientific and Laboratory Services, Pall Life Sciences

Mani Krishnan, Program Director, Single-Use Processing Systems, EMD Millipore

Robert Repetto, Director, External Affairs, BioTherapeutics Pharmaceutical Sciences, Pfizer

12:15 *Workshop Ends; Lunch on your own*

12:30 *Main Conference Registration Begins*

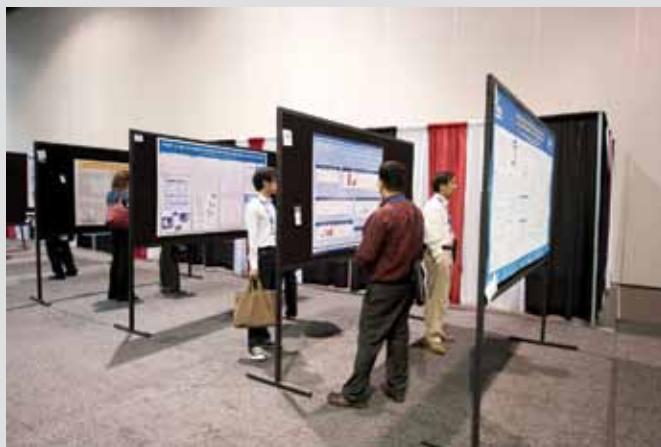
Present a Poster to Enhance Your Conference Experience

Sharing your research with your peers could lead to exciting opportunities for you to advance your career.. and it can help justify the time and cost of your attendance at the conference.

The deadline to submit an abstract & be included in the conference documentation is August 12, 2011 (full payment for conference and poster fee must be received by this date.) After that date posters are on a space available basis. New poster size: Maximum dimensions of 36" wide (3 feet) x 48" high 4 (feet). To submit your poster and for additional details on the poster sizes and regulations, please visit

www.IBCLifeSciences.com/BMD

Share your research with your peers and make your mark in this field – it could lead to exciting opportunities to advance your career.



1:25 **Chairperson's Opening Remarks**

Randy Maddux, Vice President, Manufacturing Operations, Human Genome Sciences, Inc.

Keynote Presentations1:30 **Deploying Business Process Excellence in Biologics Manufacturing**

Genentech Oceanside deployed Business Process Excellence in 2007. By the summer of 2009 Oliver Wight International recognized them for achieving "Class A" certification with their production operations. Greater than 80% of companies embarking on this improvement journey fail to be certified by Oliver Wight. Learn about this intriguing transformation from the person tasked to get this initiative off the ground and to achieve Class A certified operations within two years.

James R. Kasselmann, Director, Clinical Manufacturing, Genentech, Inc.

2:05 **Next Generation Process in a New Biotechnological Facility**

Is high titre everything? How can "right first time" be achieved during technology transfer (TT) into a new facility? How should obstacles be handled to minimise their impact on timeline and cost? How will TT be affected by the fact that more facilities must accommodate multiple products? Hear an analysis of the technical capabilities and additional interaction required to get new processes into already existing facilities in the context of Pfizer's new award-winning facility.

Kim Sandell, Director, Operations Management & Operational Excellence, Pfizer, Sweden

2:40 **Amgen's Perspective on Manufacturing of the Future**

A new paradigm, in which biotechnology products can be manufactured more efficiently and more cost-effectively than today, is essential. Our analysis of cost pressures, new technologies and ever changing products and markets suggests that increased manufacturing flexibility will be required for the future. Technology advancements and a new operating philosophy will allow Amgen to successfully transition and prepare for the future.

Stephen J. Hill, Executive Director, Manufacturing Technology, Amgen

3:15 *Networking Refreshment Break; Opening of Poster and Exhibit Hall*

4:00 **What's Next after Achieving Rapid Capacity Increase and Flexibility through the Use of Disposables?**

BioMarin recently completed construction, qualifying and commenced processing in its newly expanded facility for commercial and clinical products. The facility start-up time was greatly reduced by implementation of numerous disposable systems and applications. This talk will touch upon the scope and processes BioMarin used to design and implement systems but will focus on current efforts to improve existing systems, integrate engineering and automation controls and challenge the concept of "single-use."

Chris M. Brodeur, Senior Operations Manager, Commercial Manufacturing, BioMarin Pharmaceuticals

4:35 **Shire's Manufacturing Strategy and New Flexible Facility: Completely Disposable Upstream and Traditional Stainless Downstream**

Abstract unavailable at press date. Please visit www.IBCLifeSciences.com/BMD for program updates.

James Stout, Ph.D., Associate Director, Purification PD, Shire Human Genetic Therapies

5:15 **Networking in Poster and Exhibit Hall**

"IBC conferences provide a platform to understand/gauge the best practices of the industry, thus a great opportunity to benchmark oneself!"

– **Srinivasan Raman**, General Manager, Operations, Biologics Manufacturing, Biocon, India

8:00 *Networking Coffee*

Enabling Flexible Facilities**Strategic Decisions for Enabling Flexible Facilities**8:30 **Chairperson's Opening Remarks**

Sourav K. Kundu, Ph.D., Director, Process Development, Amgen

8:45 **NEW UNPUBLISHED DATA CASE STUDY A Risk-Based, Scientific Approach to Multi-Product Operations**

Many biologics manufacturing facilities produce multiple products. This requires rapid and cost effective changeovers in between product campaigns in order to preserve capacity and control costs. This talk will describe ImClone's risk-based, scientific approach to multi-product operations and product changeovers in its multi-product manufacturing facility. This facility produces materials from multiple cell lines for both clinical and commercial use.

Todd D. Winge, Vice President, Biologics Manufacturing, Process Engineering, and Logistics, ImClone Systems, a wholly owned subsidiary of Eli Lilly and Company

9:15 **NEW UNPUBLISHED DATA CASE STUDY Incorporation of Disposable Technology Platforms into Existing Biopharmaceutical Facilities**

Hospira is involved in the development and manufacture of high quality biosimilar products. This presentation will focus on the challenges and benefits of deploying multiple manufacturing platforms within the same facility, with a focus on case studies describing specific issues and solutions. The comparative costs, space utilization considerations, product development benefits and quality implications of these competing manufacturing platforms will be discussed.

Meera M. Verma, Ph.D., Director, Site Operations, Global Biologics R&D, Hospira, Australia

Biomanufacturing Excellence**Continuous Processing**8:30 **Chairperson's Remarks**

Rick Johnston, Co-Director, Center for Biopharmaceutical Operations, University of California, Berkeley

8:45 **Can Continuous Purification of Biopharmaceuticals Become a Reality?**

Most biopharmaceutical products are manufactured using "tried and true" batch processing methods, which are effective but inherently less capital-efficient than continuous processing methods. Adoption of continuous processing approaches presents challenges, including regulatory uncertainties and the design and complexity of conventional continuous-processing equipment. This talk will focus on approaches that may be used to address these challenges and realize implementation of continuous processing technologies for biopharmaceutical manufacturing.

Thomas C. Ransohoff, Vice President, BioProcess Technology Consultants, Inc.

9:15 **NEW UNPUBLISHED DATA CASE STUDY Stepping into the Future Continuously – Working towards an Integrated Antibody Purification Process**

To address the inefficiencies associated with traditional batch-based protein purification processes, it is desirable to integrate individual downstream unit operations into a single continuous paradigm. This presentation will focus on the use of emerging technologies to construct a continuous, disposable bioprocess specifically focused on the integration of the initial steps in a platform CHO-based antibody purification process.

Mark A. Brower, Ph.D., Senior Research Chemical Engineer, Biologics New and Enabling Technologies, Merck & Co., Inc.

Enabling Flexible Facilities

Strategic Decisions for Enabling Flexible Facilities (continued)

- 9:45 **NEW UNPUBLISHED DATA** **CASE STUDY** **Flexible Manufacturing Facility Using Disposable Technology**
Hear Biogen Idec's case study on their flexible manufacturing strategy, development design, and regulatory experience with disposable facilities.
Lynn Conley, Associate Director, Technical Development, **Biogen Idec**
- 10:15 *Networking Refreshment Break, Exhibit and Poster Viewing*
- 10:45 **CASE STUDY** **Small Scale Monoclonal Antibody Manufacturing Sourcing: Financial Analysis and Decision-Making Process for CMO vs. In-House Manufacturing**
Manufacturing of small scale biologics drug substance for early stage clinical trials presents unique challenges when balancing between costs and meeting tight clinical trial timelines. This presentation discusses a case study of the Make vs. Buy analysis for small-scale manufacturing of clinical monoclonal antibody clinical material. Manufacturing costs, timelines and optimization of the internal manufacturing network are considered.
Polina Rapoport, Site Manager, Pharma Technical Manufacturing Development, **Genentech, Inc.**
- 11:15 **The Reality of Closed Single Use Processing: Maximizing your Gray Space**
As has been the case with the advent of any new manufacturing technology, the immortal allure of closed processing has raised interest in what advantages single use technology may provide. The presentation will discuss some of the facts and myths of closed processing and how single use technologies enable or hinder the implementation of an entirely closed manufacturing capability.
Parrish Galliher, President and Chief Technology Officer, **Xcellerex, Inc.**
- 11:45 **Technology Workshop** **Scalability and Flexibility in Single-Use Technology**
Sponsored by: **Thermo SCIENTIFIC**
Single-Use Technologies (SUT) support most production train segments with advantages in capital investment, COG, safety, scheduling, surge capacity and process replication. Optimization in bench-top SUT is now transferred to 2000L SUT reactors, while maintaining similar probes, porting, and control. "Flexible manufacturing" maintains cGMP while accommodating campaign schedule and production scale change; reconfigurability for multiple product portfolios; and multiple production platforms.
William G. Whitford, Senior Manager, Marketing, **Thermo Fisher Scientific**
- 12:15 *Luncheon in Exhibit and Poster Hall*

Scale Up and Guidance for Implementation

- 1:40 **Chairperson's Remarks**
Adam Goldstein, Principal Scientist, **Genentech, Inc.**
- 1:45 **Approaches to the Use of Disposables for Clinical Manufacturing at Alexion's Rhode Island Manufacturing Facility (ARIMF)**
Manufacture of Alexion's diverse product pipeline requires multiple manufacturing processes. This necessitates a flexibility manufacturing facility. Historical use of disposables at ARIMF and new opportunities under consideration will be discussed. A cost/benefit comparison of select disposables to fixed equipment will also be presented. This comparison will consider material costs, shelf life, volume flexibility, scheduling constraints, and product impact risk reduction.
Alfred W. Boyle, Ph.D., Director, Technical and Clinical Manufacturing Services, **Alexion Pharmaceuticals**
- 2:15 **NEW UNPUBLISHED DATA** **The Introduction of Disposables into Drug Product Operations on a Large Scale Basis**
Disposables have been utilized in the biopharmaceutical industry to increase efficiency and reduce manufacturing cost. Disposable use in drug substance manufacturing processes has matured from buffer bags to fully disposable unit operations. Until recently, most filling operations were done with standard equipment. The presentation discusses new technologies and implementation strategies that will bring the cost and efficiency benefits of disposables to drug product manufacturing.
Kellen Mazzarella, Engineer 2, Pharmaceutical Processing and Technology Development, **Genentech, Inc.**

Biomanufacturing Excellence

Continuous Processing (continued)

Panel Discussion

- 9:45 **Continuous Processing** Sponsored by: **PALL** Life Sciences
New Science. New Thinking.™
Moderator:
Thomas C. Ransohoff, Vice President, **BioProcess Technology Consultants, Inc.**
Panelists:
Mark Brower, Ph.D., Senior Research Chemical Engineer, **Biologics New and Enabling Technologies, Merck & Co., Inc.**
Jon Petrone, Vice President, Technical Services, **Pall Life Sciences**
Additional panelists to be announced
- 10:15 *Networking Refreshment Break, Exhibit and Poster Viewing*
- 10:45 **Technology Workshop** Sponsored by: **PALL** Life Sciences
New Science. New Thinking.™
Achieving High Concentration Antibody Formulations using Single-Pass TFF
Single-pass TFF technology can be used to concentrate protein solutions to high levels in a single pump pass. The technology results in more compact systems than traditional TFF due to its reduced flow rate requirements and simple control methods. This presentation will focus on performance data for the concentration of antibody solutions to >200 g/L with high product recovery.
Jon Petrone, Vice President, Technical Services, **Pall Life Sciences**

Continuous Improvements to Improve Speed, Cost Savings and Competitiveness

- Chairperson: **Peter Latham**, President, **Latham BioPharm Group**
- 11:15 **NEW UNPUBLISHED DATA** **CASE STUDY** **Process Adaptations and Improvements in Commercial Biologics Manufacturing for Increased Robustness and Risk Mitigation**
Applying new technologies driven out of development in new and existing manufacturing processes and assets becomes more important to increase efficiency, mitigate risk (financial & supply chain risk) without compromising quality. A case study focusing on necessary process adaptations due to facility fit and the implementation of several new technologies (e.g. HTST, disposables) will be presented and discussed in this presentation.
Michael Pohlscheidt, Ph.D., EMBA International SCM, Associate Director, Manufacturing Sciences and Technology, **Oceanside Product Operations, Genentech, Inc.**
- 11:45 **NEW UNPUBLISHED DATA** **Strategies for the Development and Manufacturing of Biosimilars**
The availability of biosimilars is one of the obvious solutions to increase the accessibility of protein therapeutics for patients and to lower the healthcare cost for the societies. The strategies of developing and manufacturing biosimilars with high quality and low cost to meet the requirements will be presented.
Judy Chou, Ph.D., Vice President, Research and Development, **Tanvex Biologics Inc.**
- 12:15 *Luncheon in Exhibit and Poster Hall*

Supply Chain Risk Mitigation

- 1:40 **Chairperson's Remarks**
Myles Marcus, Vice President, Supply Chain Management, **Dendreon Corporation**
- 1:45 **Supply Chain Risk and Sole Sourcing: Survey Results and Lessons from Other Industries**
Lean supply chain efforts in many industries have resulted in firms moving towards sole sourcing arrangements. By eliminating redundancy, a key risk mitigation tool, these arrangements lead to a need for alternative risk management approaches. In this presentation, we explore results of our ongoing survey of biopharmaceutical supply chain risks, and discuss lessons learned from our work with other industries.
Phil Kaminsky, Ph.D., Professor; Director, Initiative for Research in Biopharmaceutical Operations, Industrial Engineering and Operations Research, **University of California, Berkeley**

Enabling Flexible Facilities

Scale Up and Guidance for Implementation (continued)

2:45 Technology Workshop

Strategies for Single-Use in Tangential Flow Filtration Applications

Sponsored by:  novasep

TFF is a common processing step in downstream processing for concentration and diafiltration of biopharmaceutical products. Utilizing a single-use approach can reduce labor and buffer/water usage by respectively 50% and 75% or more. Novasep offers the first pre-sanitized, single-use TFF cassette for biopharmaceutical applications. Each SIUSTM cassette is delivered pre-sanitized, ready to be equilibrated and used for processing. This presentation explores case studies for single-use TFF in biopharmaceutical applications.

Presenter to be announced

3:15 Refreshment Break and Last Chance for Poster and Exhibit Viewing

4:00 Panel Discussion: Update on Industry Approaches towards Harmonization of Data Sources Regarding Disposables

Moderator: **Paul B. McCormac, Ph.D.**, Senior Manager, Biomanufacturing Sciences Group, Pfizer Global Manufacturing

Introduction to the Discussion:

Industry Data Sources Website: A Collection of Industry Abstracts of Single-Use and Disposable Documents and Articles – A Collaborative Effort by ISPE, BPE, BPSA and PDA

Learn about the benefits of an online directory where industry professionals can access white papers, technical reports and documents, and articles relating to implementation, waste management of disposable technologies, ROI determinations, validation, and other key issues concerning the conversion to single-use/disposable processes.

Representing ISPE Disposables Group:

Ken Baker, CEO, NewAge Industries / AdvantaPure

Adam Goldstein, Principal Scientist, Genentech, Inc.

Development of a Quality Agreement Template for Single-use Suppliers and Users

Using established templates developed by FDA for contract biological manufacturing, by IPAC-RS for OINDP manufacturing, and SOCMA for bulk pharmaceutical manufacturing, the BPSA has undertaken to develop a Quality Agreement Template for single-use manufacturing that will aid suppliers and users in establishing formal quality agreements. An update on ELSIE activities will also be provided.

Representing BPSA:

Jerold Martin, Senior Vice President, Scientific Affairs, Pall Life Sciences;

Chairman, Bio-Process Systems Alliance

PDA Task Force for Single Use Systems, Presents a Technical Report Overview

The lack of a roadmap and best practices for the implementation of single use technologies in pharmaceutical manufacturing has been a recognized challenge within the industry. The Parenteral Drug Association has developed a technical document establishing a framework by which organizations can establish a manufacturing strategy for implementing single use technologies with special consideration for their individual needs, goals and competencies.

Robert Repetto, Director, External Affairs, BioTherapeutics Pharmaceutical Sciences, Pfizer

Audience Interactive Discussion

Panelists will include presenters listed above as well as:

Representing ASME-BPE:

Ted Hutton, Business Development Manager, Arkema Inc.; Chairman, ASME BPE Polymer Material (PM)

5:30 Close of Tuesday Sessions

Biomanufacturing Excellence

Supply Chain Risk Mitigation (continued)

2:15 Mitigating the Impact of Raw Materials: A Risk-Based Approach

Raw materials constitute one of many factors that can influence the successful and consistent performance of a biopharmaceutical manufacturing process. Such raw materials can significantly impact process outputs, such as: product quality and safety, productivity, process consistency and impurity profiles. This overview provides a systematic, risk based approach to managing raw materials throughout a product lifecycle.

Paul Lewus, Ph.D., Principal Engineer, Product and Process Engineering, Amgen Inc.

2:45 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 Sherry Johnson at (508) 614-1451 or sjohnson@ibcusa.com.

3:15 Refreshment Break and Last Chance for Poster and Exhibit Viewing

Risk Management Approaches to Process Design and Technology Transfer

Chairperson: **Rick Johnston, Ph.D.**, Executive Director, CELDI Center for Research in Biopharmaceutical Operations, University of California at Berkeley

4:00 **NEW UNPUBLISHED DATA** **CASE STUDY** Prediction of Mammalian Cell-Culture Performance and Product Quality Attributes with Analytical Measurements of Raw Material Ingredients

Raw materials and media, cell-cultures and product quality attributes are characterized with analytical spectroscopy and multivariate calibration models. Their correlations are quantified and investigated if one can obtain information for raw material lot screening, consistency increase of cell-culture performance, and productivity increase. Preliminary data indicates possibility of paradigm shift for cell-culture operation from "recipe-based" to "process control."

Seongkyu Yoon, Ph.D., Assistant Professor, Chemical Engineering and Massachusetts Biomanufacturing Center Director, University of Massachusetts, Lowell

Andrew Christie, Ph.D., Principal Scientist, SAFC Biosciences

4:30 **NEW UNPUBLISHED DATA** **CASE STUDY** Advanced Process Control: Discrete Data Multivariate Models for Chromatography Monitoring

Characterizing the relationship between input and output variables of chromatography operations is critical to process monitoring, optimization and ultimately, prediction. This presentation discusses Biogen Idec's strategy for chromatography analysis and monitoring using key process parameter discrete data. This approach leverages the power of multivariate analysis and process knowledge to enhance process understanding and improved process performance.

Robert A. Genduso, Scientist II, Manufacturing Sciences, Biogen Idec

5:00 Biomanufacturing Excellence in Early Phase Clinical Manufacturing

The application of manufacturing excellence concepts in early stage clinical manufacturing enables efficient technology transfer and improved organizational learning. This presentation will review some of key concepts employed at HGS and their impact on technology transfer.

Justin R. Horvath, Senior Project Coordinator, Technical Services, Human Genome Sciences

5:30 Close of Tuesday Sessions

Novel Downstream Technologies for Managing High Titters including Disposables

Session sponsored by **Lonza**

8:20 Chairperson's Remarks

Todd D. Winge, Vice President, Biologics Manufacturing Process Engineering, & Logistics, **ImClone Systems**, a wholly owned subsidiary of **Eli Lilly and Company**

8:30 A Comparison of Protein A, Non-Protein A, and Disposable Downstream Processes for a Monoclonal Antibody from Fed-Batch and Intensified Cell Culture Harvests

Advances in downstream technologies have addressed many challenges in the purification of mAbs, such as reducing cost and time by introducing high capacity capture steps and single-use technologies. This study compares three mAb purification processes: a Protein A based process as a benchmark for comparing a high capacity ion exchange (column based) process and a process based on single-use technologies.

Michael Kuczewski, Scientist I, **Percivia LLC**

9:00 **NEW UNPUBLISHED DATA** **CASE STUDY** Development of an Alternative Monoclonal Antibody Polishing Platform

In this study Sartorius Sartobind® STIC was evaluated as a mAb polishing step. Utilizing a combination of HTS screening and DOE optimization, we developed a mAb polishing platform which demonstrated a high step recovery, and efficient clearance of impurities for multiple antibodies. This simple and efficient polishing step may shorten mAb purification processes, reduce production costs, and accelerate development programs.

Yun (Kenneth) Kang, Ph.D., Senior Scientist, Head of Purification Team, Bioprocess Sciences, **ImClone Systems**, a wholly-owned subsidiary of **Eli Lilly and Company**

9:30 **NEW UNPUBLISHED DATA** **CASE STUDY** Integration of Disposable Technologies to Enable Downstream Purification of High Titer Processes in Existing Manufacturing Facilities

Recently we faced the challenge of transferring 3 new processes into our facility in Portsmouth, NH which each had higher titer processes than the facility was designed for. New capital investments are typically required to handle higher titers and the consequently higher process / buffer volumes in the purification suites. The choices we faced with respect to capital investments (fixed system vs. disposables), the selection criteria employed, and lessons learned will be presented.

Robert Grassi, Group Manager, **Lonza Biologics**

10:00 Networking Refreshment Break

Scientific Advisory Committee

Adam Goldstein, Principal Scientist, **Genentech, Inc.**

Rick Johnston, Ph.D., Executive Director, **CELDI Center for Research in Biopharmaceutical Operations**, **University of California at Berkeley**

Sourav K. Kundu, Ph.D., Director, Process Development, **Amgen**

Peter Latham, President, **Latham BioPharm Group**

Randy Maddux, Vice President, Manufacturing Operations, **Human Genome Sciences, Inc.**

Ekta Mahajan, Senior Engineer, **Genentech, Inc.**

Myles Marcus, Vice President, Supply Chain Management, **Dendreon Corporation**

Paul B. McCormac, Ph.D., Senior Manager, Biomanufacturing Sciences Group, **Pfizer Global Manufacturing**

Todd D. Winge, Vice President, Biologics Manufacturing Process Engineering, & Logistics, **ImClone Systems**, a wholly owned subsidiary of **Eli Lilly and Company**

10:30 **NEW UNPUBLISHED DATA** A 'Fully' Disposable Primary Recovery Step for Harvesting Mammalian Cell Culture Systems: Focus of Depth Filtration technologies

The advent of highly productive cell-culture processes for the production of recombinant proteins has driven smaller batch processing that provides opportunity for transforming conventional bioprocess trains into single-use operations. We will be discussing the implementation of a 'fully' disposable primary recovery step using Depth filtration technologies for harvesting recombinant proteins from high cell density cell cultures containing mammalian cells. We will provide a technical overview of conventional Depth filtration performance capabilities and novel processing techniques including the pros and cons for implementing these clarification technologies.

Jonathan Romero, Ph.D., Senior Engineer, Biopharmaceutical Development, **Biogen Idex**

11:00 Implementation of Disposable Depth Filtration Solutions for GLP and GMP Applications

Implementation of disposable depth filtration solutions improve facility flexibility, reduce project timelines, and reduce costs which are all critical factors in the contract manufacturing environment. Currently, multiple formats from different vendors cover small scale development through commercial manufacture, allowing for linear scale up from small scale development, and promoting maximum flexibility while minimizing capital investments.

Beth McCooley, Senior Manufacturing Scientist, **PacificGMP**

11:30 Facility Debottlenecking through the Use of Simplified Buffer Systems for Antibody Manufacturing Process

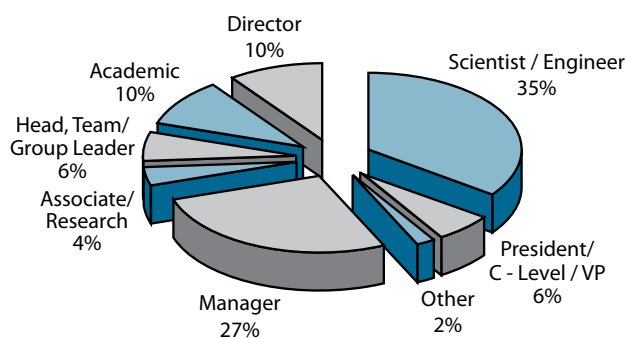
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Natraj Ram, Ph.D., Senior Group Leader, Purification, Technical Operations, **Abbott Bioresearch Center**

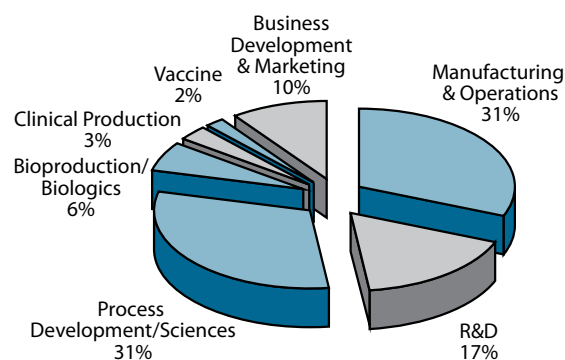
12:00 Close of BMD Summit

Who You Will Meet

Job Titles



Departments



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Stacey M. Kaneshiro, Senior Consultant Engineer, Eli Lilly and Co.

“This will be a great opportunity to learn what other specialists are doing in the disposables for biotech arena.”

James W. Chrostowski, Ph.D., Engineer III, Biogen Idec

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Srinivasan Raman, General Manager, Operations, Biologics Manufacturing, Biocon, India

Keynote Presentations

**Deploying Business Process Excellence
in Biologics Manufacturing**



James R. Kasselmann
Director, Clinical
Manufacturing
Genentech, Inc.

**Next Generation Process in a New
Biotechnological Facility**



Kim Sandell
Director, Operations
Management & Operational
Excellence, Pfizer, Sweden

**Facility of the Year Award:
Operational Excellence**

**Amgen's Perspective on
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Stephen J. Hill
Executive Director
Manufacturing Technology
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