The largest bioprocessing event bringing you new ideas, demystifying technology, and fostering partnerships in highly engaging formats to move drug candidates closer to approval

The Most Comprehensive Science
Capitalize on the latest data-driven research and moderated discussions to move towards commercialization and streamlined development and production from upstream to drug product/fill-finish

The Most Innovative Technologies
Accelerate speed, efficiency and ROI across a global network by evaluating innovative and proven products and services at the industry’s largest exposition

The Right Partners for You
Form collaborations and alliances with innovators, suppliers, academia and associations to reach new heights of clinical and commercial success

Register by July 17 and Save $400 – Learn more and register today at www.IBCLifeSciences.com/BPI
BPI is engineered to be exactly what YOU need it to be. Formal and informal networking experiences connect you to peers, prospects, and customers. Parallel tracks give you the option to dive deep or take a big picture approach to learn about industry trends, challenges, and benchmark against the latest research developments.

Big pharma and large, mid-size and emerging biotechs collaborating with solution providers featuring proven and next generation technologies make BPI a one-of-a-kind meeting place.

**Back by Popular Demand!**
BPI Theater, a curated showcase of the best innovations.

**New and Improved!**
BPI Connect Partnering App to help jump start your next partnership or collaboration

**NEW!** Exposition Hall Tour for focused exhibit viewing led by an industry insider.

**NEW!** 15 Bioprocessing Problem-Solving Moderated Discussions to help you move drug candidates closer to approval.

**NEW!** Ask the Regulators Open Forum that will answer your critical questions about regulatory expectations.

6 tracks for one fee.
Go specialized or expand your horizons across disciplines for a personalized, curated content experience.

NEW! Town Hall Forums for highly focused industry best practice sharing.

For up-to-date program information and new abstracts, visit: [www.IBCLifeSciences.com/BPI](http://www.IBCLifeSciences.com/BPI)
Cell Culture & Upstream Processing

Process development scientists, engineers and technical experts share their recent achievements in reducing timelines and COGs while increasing efficiency and productivity through implementation of disruptive approaches and technologies across all stages of cell culture.

Manufacturing Strategy

Biomanufacturing experts share strategies to maximize efficiencies and cost savings across your manufacturing network through implementation of disruptive technologies, operational excellence and new facility concepts. Learn how to develop your manufacturing infrastructure so you can remain flexible to the production needs of a diverse pipeline of novel biologic molecules in a multiproduct environment.

Analytical, Formulation and Quality

Thought-leaders in the field help you to stay abreast of emerging analytical tools and formulation strategies for mAb, non-mAb and next generation biotherapeutics. Learn about the impact of increasing quality expectations for your products and processes so you can optimize your analytical and formulation strategy and reduce quality risk across the product lifecycle.

Recovery and Purification

Building on the momentum being gained from the innovation of methodologies, materials science and technologies, companies will describe progress being made to optimize efficiencies, process design and flexibility in downstream processing for an emerging wave of antibodies and novel modalities.

NEW! Drug Product Manufacturing & Fill-Finish Processing

Explore the technologies, strategies and solutions involved in moving from API (drug substance) to finished drug product ready for human use. Case studies and real world experiences will be presented to highlight potential pitfalls and challenges for a variety of different products. An evaluation of emerging technologies and creative drug product solutions will also be presented.

Early Stage Biologics and Companies

Learn how to accelerate the transition from biologics discovery to IND and beyond by implementing these key strategies and critical development activities. Learn from experts who will help guide you through the steps you need to take to help you reduce your risk, development timeline and costs, while maximizing the chance of success for your new products.

For up-to-date program information and new abstracts, visit: www.IBCLifeSciences.com/BPI
## Agenda at-a-Glance

### Monday, October 26, 2015 • Pre-Conference Symposia

<table>
<thead>
<tr>
<th>Morning</th>
<th>Afternoon</th>
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<tbody>
<tr>
<td>Cell Therapy Bioprocessing</td>
<td>ADC Development &amp; Production</td>
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<tr>
<td>Innovation in Process and Product Development Technologies for Biopharmaceutical Development Sponsored by 3M</td>
<td>Future of Biomedicine and Biomanufacturing</td>
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<tr>
<td>Two-Day Training Courses (details on page 18)</td>
<td>Two-Day Training Courses</td>
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### Tuesday, October 27, 2015 • Main Conference

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<tr>
<th>8:00-9:45</th>
<th>9:45-10:15</th>
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<tbody>
<tr>
<td>Cell Culture &amp; Upstream Processing</td>
<td>Networking Refreshment Break</td>
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<tr>
<td>Recovery &amp; Purification</td>
<td>Process Characterization, QbD and Technology Transfers</td>
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<tr>
<td>Drug Product Manufacturing &amp; Fill-Finish Processing</td>
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<tr>
<td>Manufacturing Strategy</td>
<td>Drug Product Manufacturing &amp; Fill-Finish Processing</td>
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<td>Cell Culture &amp; Upstream Processing</td>
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<td>Recovery &amp; Purification</td>
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<tr>
<th>10:15-11:45</th>
<th>11:50-12:20</th>
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<tr>
<td>Technology Workshops Sponsored by: Sartorius Stedim Biotech, GE Healthcare, BIA Separations, MaxCyte</td>
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<td>10:30-12:00</td>
<td>12:05-12:35</td>
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<tr>
<td>Tuesday, October 27, 2015 • Main Conference</td>
<td>Tuesday, October 27, 2015 • Main Conference</td>
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<tr>
<td>1:25-3:00</td>
<td>3:10-4:45</td>
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<tr>
<td>Integration of Process Analytics</td>
<td>Keynote Presentations</td>
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<tr>
<td>Novel Approaches for Non-Chromatographic Purification of Proteins</td>
<td>Environment, Sustainability, and Energy Efficiency in Biopharmaceuticals</td>
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<tr>
<td>Integrating Drug Substance and Drug Product Manufacturing</td>
<td>Case Studies</td>
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<td>Continuous Processing and Building in Manufacturability</td>
<td>Case Studies</td>
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<tr>
<td>Biosimilar Product Quality, Characterization and Comparability</td>
<td>Case Studies</td>
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<tr>
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<td>BPI Theater</td>
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<td>Exposition Hall Hours: 9:45 am - 7:00 pm</td>
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### Thursday, October 29, 2015 • Main Conference

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## Schedule subject to change

Register Early for Best Savings • www.IBCLifeSciences.com/BPI • 800-390-4078
### Cell Therapy Bioprocessing

**Sponsored by:** Pall Life Sciences

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>8:30</td>
<td>Chairperson’s Opening Remarks and State of the Industry Address</td>
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<tr>
<td></td>
<td>Anthony Davies, President, Dark Horse Consulting</td>
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<tr>
<td>9:00</td>
<td><strong>Cell Therapy Process Development</strong></td>
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<td></td>
<td>Automated iPSC Culture Process</td>
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<td></td>
<td>Wen Bo Wang, Ph.D., Vice President, Process Sciences, Cellular Dynamics International</td>
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<tr>
<td>9:30</td>
<td>Solutions to Process and Technology Bottlenecks</td>
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<td></td>
<td>Nick Timmins, Ph.D., Director, Product and Process Development, Centre for Commercialization of Regenerative Medicine (invited)</td>
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<tr>
<td>10:00</td>
<td>Networking Refreshment Break</td>
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<tr>
<td>10:30</td>
<td><strong>Tools and Technologies</strong></td>
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<td></td>
<td>Presentation Sponsorship Opportunity</td>
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<tr>
<td></td>
<td>If you have a novel cell therapy technology and are interested in sponsoring a presentation in this session, please contact Jennifer Wicket at <a href="mailto:jwickett@ibcus.com">jwickett@ibcus.com</a> or Kristen Schott at <a href="mailto:kschott@ibcus.com">kschott@ibcus.com</a></td>
</tr>
<tr>
<td>11:00</td>
<td>Advancing the CRISPR/Cas9 Technology Platform for Therapeutic Applications</td>
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<tr>
<td></td>
<td>Grant Welstead, Ph.D., Research Scientist, Editas Medicine</td>
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<tr>
<td>11:30</td>
<td><strong>Featured Presentation</strong></td>
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<td>Update on Japan’s New Regulations – What is Going on in Japan and How Will It Impact the Rest of the World?</td>
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<td></td>
<td>David Hall, CEO &amp; President, RepliCel Life Sciences</td>
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<td>11:50</td>
<td>Networking Luncheon</td>
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### ADC Development & Production

**Sponsored by:** Pall Corporation

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<tr>
<td>9:00</td>
<td>Chairperson’s Opening Remarks</td>
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<td></td>
<td>Pranitha Reddy, Ph.D., Consultant, Gene to BLA, LLC</td>
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<tr>
<td>9:15</td>
<td><strong>New Modalities and Next Generation ADCs</strong></td>
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<tr>
<td></td>
<td>Featured Presentation</td>
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<td></td>
<td>New Payloads for ADCs: Challenges and Advantages</td>
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<td>Ravi J. Chari, Ph.D., Executive Director, Chemistry and Biochemistry, ImmunoGen, Inc.</td>
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<tr>
<td>9:45</td>
<td>ADCs: Leveraging Shared Learnings to Enable Next Generation Success</td>
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<tr>
<td></td>
<td>Alan C. Rigby, Ph.D., Vice President, ADC Biology, Eli Lilly and Company</td>
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<tr>
<td>10:15</td>
<td>Expressed Protein Ligation as a Bioconjugation Platform</td>
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<td></td>
<td>Oliver R. Thiel, Ph.D., Principal Scientist, Process Development, Amgen Inc.</td>
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<tr>
<td>10:45</td>
<td>Networking Refreshment Break</td>
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<tr>
<td>11:15</td>
<td>Overcoming Challenges and Ensuring Production of Antibodies for Site-Specific Antibody-Drug Conjugates</td>
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<td></td>
<td>Marie Zhu, Ph.D., Director of Process Sciences &amp; Manufacturing, Agensys Inc.</td>
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<tr>
<td>11:45</td>
<td>Tuning the Efficacy of Antibody Drug Conjugates Via Site-Selective Conjugation</td>
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<td></td>
<td>Alan Wahl, Ph.D., Vice President, Research and Development, Amgen Inc.</td>
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<tr>
<td>12:15</td>
<td>Networking Luncheon</td>
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**For up-to-date program information and new abstracts, visit:** www.IBCLifeSciences.com/BPI
Innovation In Process and Product Development Technologies for Biopharmaceutical Development

Sponsored by: 3M

Any registered attendee may attend this symposium at no additional charge.

9:00 Chairperson's Opening Remarks
Abhinav Shukla, Ph.D., Vice President, Process Development & Manufacturing, KBI BioPharma

9:15 Alternatives and Innovations in Technologies in Drug Substance Process Development
Chetan Goudar, Ph.D., Director, Pre-Pivotal Drug Substance Process Development, Amgen

9:45 Tools, Technologies, and Business Practices that can Accelerate the Pace of Biopharmaceutical Development
Andrew Tustian, Ph.D., Senior Scientist, Regeneron, Inc.

10:15 Innovation in mAb Processes for Companion Pets
Michael J Dupuis, Ph.D., Senior Principal Scientist, Zoetis

10:45 Networking Refreshment Break

11:15 Developing Platform Processes Across Drug Molecules
Tim Hill, Ph.D., Director, Process Development, Fujifilm Diosynth

11:45 Innovation in Harvest/Clarification Unit Operation in Bioprocess Development
Nripen Singh, Ph.D., Process Development Engineer, Bristol-Myers Squibb

12:15 Networking Luncheon

2:00 New Technologies for Platform Based Development of Antibody Processes
Kumar Dhanasekharan, Ph.D., Director, Process Development, Cook Pharmica LLC

2:30 Novel Technologies for Process Development in Monoclonal Antibody Purification
Glen Giese, Ph.D., Group Leader, Purification Development, Genentech, Inc.

3:00 Networking Refreshment Break

3:30 New Technologies in Bioprocess Development
Pete Gagnon, M.S., Group Manager, Downstream Processing, Bioprocessing Technology Institute, Singapore

4:00 Next Generation Protein A Media for mAb Purification and Development
Alexei Voloshin, Manager, Global Scientific Services Leader, 3M

4:30 Panel Discussion - Opportunities for More Holistic Approach to Biopharmaceutical Purification
Moderator: Abhinav Shukla, Ph.D., Vice President, Process Development & Manufacturing, KBI BioPharma

Panelists:
Chetan Goudar, Ph.D., Director, Pre-Pivotal Drug Substance Process Development, Amgen
Pete Gagnon, M.S., Group Manager, Downstream Processing, Bioprocessing Technology Institute, Singapore
Tim Hill, Ph.D., Director, Process Development, Fujifilm Diosynth

5:00 Close of Symposium

Present a Poster to Showcase Your Novel Research
Share your latest research by presenting a scientific poster during the event. All posters will be displayed in the Exposition Hall for fellow attendees to view and discuss. Poster presenters will be asked to stand by their posters during dedicated poster viewing hours to facilitate networking. All poster submissions are eligible for the Best Poster Award competition sponsored by BioProcess International Magazine. Two winning posters, one academia/industry and one supplier, will be announced live at the BPI Theater and have the opportunity to deliver an oral presentation.

The deadline to submit your poster abstract is September 25, 2015. For more details and to submit your poster abstract, visit www.IBCLifeSciences.com/BPI.

Want to earn a FREE pass to BPI? Become a Guest Blogger*
Earn a complimentary all-access pass by serving as a Guest Blogger pre and post event. The blogger’s responsibilities will include submitting relevant content from now until the conference, attending specifically assigned sessions at the event and blogging live or same day. Plus, you will also gain exposure through our five related blogs and more than 20 LinkedIn groups.

To apply, please contact Krista Lentini at klentini@ibcusa.com or call 646-895-7316.

*For full rules and regulations, visit www.IBCLifeSciences.com/BPI

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From recombinant insulin in 1982 to stem cell therapy for diabetes type 1 in the next decade? The biopharma industry is looking at permanent advancement in science and subsequently new therapeutic modes and molecules with the corresponding processing challenges. This crystal ball view presented by a number of experienced speakers from the industry will exemplify the potential changes in what we may deal with and how we might operate 10-20 years from now.
Optimizing Interface with Discovery and Applying ‘Omics and Systems Biology

Featured Presentation: High-Throughput Multi-Parametric Clone Screening Approach for the Generation of Tailored Production Cell Lines
Trent Munro, Ph.D., Principal Scientist, Process Development, Amgen

Next Generation Sequencing to Support CHO Cell Line Development
Stephanie Rieder, Ph.D., Principal Scientist, AbbVie

Transcriptomics of CHO Pipeline Clones with Respect to Inherent Bioprocess Properties
Wolfgang Budach, Ph.D., Lead Late Phase Process Development, BPRD, Novartis Pharma AG, Switzerland

Systems Biology – From Improving Expression to Understanding Genomic Heterogeneity and Stability
Nicole Borth, Ph.D., Professor, Department of Biotechnology, BOKU University Vienna, Austria

Applying Novel Approaches and Tools to Cell Line Engineering and Development

A Comprehensive Comparative Study Between DG44 and GS-KO Cell Line Generation Platform
Lianchun Fan, Ph.D., Senior Scientist II, Bristol-Myers Squibb

Bundling of Cell Line and Vector Technologies to Improve Expression, Stability and Timelines
Thomas Jostock, Ph.D., Senior Fellow, Novartis Leading Scientist, Biologics Technical Development & Manufacturing, Novartis Pharma AG, Switzerland

Application of CRISPR/Cas9 Technology to Improve Cell Line Development and Production
With the recent emergence of CHO genome sequences, CHO cell line engineering has taken on a new aspect through targeted genome editing. Facile genome editing using the bacterial RNA-guided CRISPR/Cas9 technology empowers researchers in the CHO community to elucidate the mechanistic basis behind high level production of proteins and product quality attributes of interest. Here, I will present the application of CRISPR/Cas9 technology for development of next generation CHO cell factories mainly focusing on knockout and knock-in approaches while highlighting both future perspectives and challenges.
Jae Seong Lee, Postdoc, Ph.D., The Novo Nordisk Foundation Center for Biosustainability, Technical University of Denmark

Technology Workshops

From Continuous Manufacturing Approaches for Single-Use Manufacturing
Christel Fenge, Vice President of Marketing for Fermentation, Sartorius Stedim North America

Optimal and Consistent Protein Glycosylation in Biosimilar Production
William G. Whitford, Senior Manager, Cell Culture, GE Healthcare

HPLC Fingerprinting for Efficient PAT
Ales Strancar, CEO, BIA Separations

Rapid Production of Recombinant Proteins and Stable Cell Lines at Different Scales
Weili Wang, Ph.D., Principal Scientist, Protein Production, MaxCyte

Cell Culture

For up-to-date program information and new abstracts, visit: www.IBCLifeSciences.com/BPI
Featured Presentation

Modeling of Glycosylation – Predicting Profiles of Glycosylation from Metabolic Data

Single glycoform monoclonal antibodies can be targeted for specific therapeutic functions. The glycosylation profile can be controlled by cellular glycoengineering, media manipulation or enzymic remodelling. Possible strategies for the use of each of these methods will be shown for the production of an antibody. The expected outcomes of such strategies will be evaluated with specific examples of commercial mAbs.

Michael Butler, Ph.D., Professor of Microbiology, University of Manitoba, Canada

Integration of Process Analytics

Process Analytics to Develop Novel Molecules
Christopher Sellick, Ph.D., Team Leader, MedImmune

Raising the Bar: Advanced Analytics in Upstream Bioprocess Development
Christopher Yu, Ph.D., Senior Scientist, Protein Analytical Chemistry, Genentech, A Member of the Roche Group

Short Break to Move to Keynote Session
Cell Culture

Wednesday, October 28, 2015 (continued)

10:25 Chairperson’s Remarks
Chandana Sharma, Ph.D., Principal Scientist, Cell Sciences and Development, SAFC

Development and Production of New Modalities

10:30 Featured Presentation
The Future of Cell Therapy
Anthony Davies, Ph.D., President, Dark Horse Consulting

11:00 Emulsification Process to Alginate Encapsulate Cells for Diabetes Therapy
James M. Piret, Ph.D., Professor, Michael Smith Laboratories & Dept. of Chemical and Biological Engineering, University of British Columbia

11:30 Development of a Scaleable and Productive Insect Cell Culture Based Process for Making Flublok, The First FDA Licensed Recombinant Influenza Vaccine
The hemagglutinin (HA) protein from the Influenza Virus has proven to be an effective vaccine. This presentation will demonstrate that the manufacturing process is reproducible and scaleable. An example is presented (for H7N9) on how the HA based vaccine process used to make Flublok by Protein Sciences is an ideal manufacturing platform for rapid response to pandemic influenza.
Barry Buckland, Ph.D., Senior Advisor, Protein Sciences

12:05 Technology Workshops

ARAGEN

Using Process and Activity to Drive Clone Selection
Oren E. Beske, Ph.D., COO, Aragen Bioscience, Inc

Single-Use Fermentation: Understanding Process Economy and Process Performance
Kenneth Clapp, Senior Global Product Manager, Bioreactors, GE Healthcare

An Insight into Recent Developments in Protein A Chromatography
Jonathan Royce, Senior Product Manager, Bioprocess Product Marketing – Downstream, GE Healthcare

For up-to-date program information and new abstracts, visit: www.IBCLifeSciences.com/BPI

1:40 Chairperson’s Remarks
Roman Rodriguez, Senior Product Marketing Leader, Upstream, GE Healthcare Life Sciences

Perfusion and Continuous Processing in Cell Culture
Sponsored by GE Healthcare Life Sciences

1:45 Mitigating Scale up and Process Challenges for a High Cell Density CHO Perfusion Process in Single-Use Bioreactors
A high cell density perfusion cell culture process utilizing a CHO cell line was developed in a 10L laboratory scale bioreactor. The process was scaled up to 200L and 2000L single use bioreactors to enable the pre-clinical and clinical production of a recombinant protein. Challenges encountered during the development, scale up and tech transfer, such as cell retention device, mass transfer, mixing, shear stress, and centrifuge perfusion capacity will be discussed.
Hang Yuan, Ph.D., Associate Director, BioProcess Development, Shire

2:15 High-Yield Production of Biologics Enabled by Perfusion and Intensification Process
Hao Chen, Ph.D., Director, Process Development & Engineering, Merck & Co., Inc.

2:45 Points to Consider for Commercial Continuous Bioprocessing
Over the last 30 years, a number of biologics have been commercially licensed that are produced by continuous bioprocessing for some portion of the production line. Today, continuous bioprocessing is being considered by more firms for development stage products and processes for a different set of industry trends, drivers and opportunities. This presentation will review the new drivers and opportunities as well as unforeseen points to consider for the commercial licensure of continuous bioprocessing.
Parrish Galliher, M.S., Chief Technology Officer, GE Healthcare

3:15 Networking Refreshment Break in the Exposition Hall
Sponsored by Pall Life Sciences

What is Driving Improvements in Efficiency, Productivity and Timelines in Cell Culture

4:00 Accelerating Time to Clinical Manufacturing Following a Targeted Gene Integration Approach
Dethardt Mueller, Ph.D., Head of Process Science, Rentschler Biotechnologie, Germany

4:30 Application of Novel Reactor Control Strategies for Upstream Bioprocess Development
In recent years, there has been a growing necessity to reduce the time, cost and risk associated to the development and scale-up of biopharmaceutical processes. The increasing pressures to reliably deliver critical quality attributes (CQAs) and process performance criteria (title, cycle time, etc.) across manufacturing and supply scales compounds this challenge. As a result, process engineering strategies, to enable streamlined, reliable and robust scale-up, have become increasingly important. Within this presentation, novel process engineering strategies and technologies that facilitate the delivery of a robust process at scale will be discussed. This is achieved by identifying and implementing effective reactor control strategies. The application of novel scale down models, advanced process control and process modelling and simulation to upstream mammalian cell culture processes will be presented and illustrated through a number of case studies.
Jessica Whelan, Ph.D., Director, Tech Operations, Process Development, APC Ltd

5:00 Identification and Control of Novel Cell Growth Inhibitors in Fed Batch Cultures
Bhanu Chandra Mulukutla, Ph.D., Senior Scientist, Pfizer

5:30 Casino Night

Networking Reception in the Exposition Hall
Feeling lucky? Wednesday night’s Networking Reception in the Exposition Hall will feature a Casino Night theme where attendees can try their luck at classic casino games like Blackjack, the Big Six Wheel, and Poker.

Co-Sponsored by BIO-RAD and GE Healthcare Life Sciences
Thursday, October 29, 2015

**Bioprocess “Problem-Solving” Discussion**
Topics and Moderators
These moderated discussions on a variety of bioprocess topics will allow you to share strategies and brainstorm solutions in an informal, small group setting.

- **QbD for Analytical Methods: Sharing Experiences and Approaches**
  Kazumi Kobayashi, Ph.D., Senior Principal Scientist, Technical Development, Biogen
- **Single-use and Disposable Technologies in Bioprocess Development**
  Wallace Lauzon, Ph.D., Senior Evaluator, Cytokines Division, CERB, BGTD, Health Canada
- **Regulatory Perspectives on Aging Facilities**
  Jeffrey Skene, Chief, Monoclonal Antibodies Division, CERB, BGTD, Health Canada
- **Inspection Trends Summary**
  Health Canada Regulator TBA
- **Regulatory Perspectives on CMC Submissions**
  Health Canada Regulator TBA
- **Particulate Defects - Critical versus Minor**
  Kevin Kerls, Inspection MSAT, Hillsboro Technical Operations, Genentech, Inc. - A Member of the Roche Group
- **Opportunities and Challenges of High Concentration Biologics**
  Mark Moody, Ph.D., Chief Scientific Advisor, ReForm Biologics
- **Development and Development: Improving the Outcome**
  Valentyn Antochshuk, Ph.D., Principal Scientist, Group Leader, Formulation Design and Process Compatibility, Merck & Co.
- **Container Closure Integrity Testing and Technology**
  Kevin M. Maloney, Ph.D., Principal Scientist, Technical Development, Biogen
- **Raw Materials Management in Biologics Production**
  Dave Kolwycz, Director, Manufacturing Sciences, Raw Material Global, Process Owner, Biogen

If you are interested in proposing or moderating a discussion topic in this breakfast session, please email at Michael Keenan mkeenan@ibcusa.com.

**High-Throughput Approaches to Process Development**

8:05 **Impact of an Accurate, Reliable, High Throughput Nutrient and Metabolite Analyzer Used in Cell Culture, Media Development, and Fermentation Process**
Jianlin (Jim) Xu, Ph.D., Senior Scientist II, Biologics Process Development, Bristol-Myers Squibb

8:30 **Mammalian Cell Culture Process Improvement Using Chemically Defined Media Via High Throughput Screening and Scale Up Production of a Monoclonal Antibody**
Cell culture process development is challenge, because of long culture time and complicated media. In this study, high throughput screening with DOE design was effectively used to improve titer by 80% with chemically defined media to replace hydrolysate media in an old process. The new process was scaled up in 500-L bioreactors with similar drug substance quality attributes.

**High Cell Density Fermentation of Micro Organisms for Production of Chemicals Using New Disposable High Throughput Ambr250™ Technology**

8:55
- **Bioprocess “Problem-Solving” Discussion**
- **Single-use and Disposable Technologies in Bioprocess Development**
- **Regulatory Perspectives on Aging Facilities**
- **Inspection Trends Summary**
- **Regulatory Perspectives on CMC Submissions**
- **Particulate Defects - Critical versus Minor**
- **Opportunities and Challenges of High Concentration Biologics**
- **Development and Development: Improving the Outcome**
- **Container Closure Integrity Testing and Technology**
- **Raw Materials Management in Biologics Production**

**Networking Refreshment Break in the Exposition Hall**
Sponsored by PALL Life Sciences

**Impact of Process Conditions on Product Quality**
10:30 **Impact of Cell Culture Conditions and Cell Age on Sequence Variance**
Karlin Anderson, Ph.D., Associate Research Fellow, Pfizer

11:00 **Perfusion and XD Process Characterization, Building Robustness to Control Product Quality**
The identification of critical process parameters can be understood through the execution of process characterization studies which can be guided by the assessment of parameter risk through failure mode effects analysis (FMEA). This case study represents the generation of process characterization data for a perfusion and XD process producing a complex recombinant biotherapeutic.

**Novel Means to Reduce Acidic Species Varients on Recombinant Antibodies and Bispecifics**
Patrick Hossler, Ph.D., Senior Scientist III, Process Sciences, AbbVie, Inc.

**Technology Workshops**
Have Your Presentation Included Here! Contact Jennifer Wickett (companies A-L) at jwickett@ibcusa.com or Kristen Schott (companies M-Z) at kschott@ibcusa.com for details.

12:35 **Networking Luncheon and Last Chance for Exposition Hall Viewing**
Performance Consistency of Platform Fed-Batch Cultures across Multiple Systems Used in Industrial Process Development

The selection of a fed-batch cultivation system is often based on throughput and cost. However, the process knowledge derived from different systems and scales is not necessarily identical. Hence, a careful evaluation of systems which are already established or newly implemented is essential. Here, we describe the performance of 10 different recombinant CHO cell lines expressing the same antibody in fed-batch culture systems ranging from a few hundred microliters to lab scale. The 10 cell lines were selected based on distinct phenotypes covering a range which can be expected in typical industrial process development projects. The cell lines were cultivated using the same expansion and fed-batch protocol. The following cultivation systems were evaluated: shaking 96-deepwell plates, 50 mL vented shake tubes, micro- and lab-scale bioreactors. The results of this study show both the limitations and the potential of each cultivation system and their suitability for process development, process characterization and scale-up.

Matthieu Stettler, Ph.D., Manager, Biotech Process Sciences, Merck Serono SA

Application of Quality by Design (QbD) Principles to the Development, Characterization and Scale-up of a Late Stage Perfusion Cell Culture Process

This case study describes our systematic QbD approach to upstream development. Our approach involved manufacturability gap analysis, process parameter risk assessment, and design of experiment studies. In parallel, computation fluid dynamics and mathematical modeling were employed to support process scale-up. Through our systematic approach, we successfully developed, characterized, scaled-up and transferred a Phase III upstream process to a CMO GMP manufacturing facility.

Tom Hayes, Process Engineer III, Late Stage Process Development, Genzyme, A Sanofi Company

Present a Poster to Showcase Your Novel Research

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The deadline to submit your poster abstract is September 25, 2015. For more details and to submit your poster abstract, visit www.IBCLifeSciences.com/BPI.
Recovery & Purification

Tuesday, October 27, 2015

7:00 Registration and Coffee
8:00 Chairperson’s Remarks
   Marc Bisschops, Ph.D., Scientific Director, Tarpon Biosystems

Implementation of Continuous Processing

8:05 Data Based Comparison of Capture and Polishing Steps in a Continuous mAb Process
   Multiple capture and polishing resins were characterized and optimized for batch manufacturing. Selected resins were characterized using a two column continuous manufacturing system. Optimized batch and continuous processes were compared for productivity, impurity, and quality measures. Data were used to compare the two manufacturing methods and determine the feasibility of continuous downstream manufacturing from the perspective of small development organization.
   John Schreffler, Ph.D., Group Leader, Purification Process Development, Eisai

8:30 Overcoming Downstream Bottlenecks in Downstream Processing
   Improved manufacturing processes are being developed to improve manufacturing network productivity and enable process fit into existing plants. Several technologies were evaluated to address these bottlenecks and help productivity including (i) newer generation protein A resins with higher binding capacity (ii) a semi-continuous mode of chromatography (sequential multi-column chromatography) for antibody capture on protein A, and (iii) single pass tangential flow filtration coupled to purification steps to enable in-line concentration of intermediate product streams. This presentation will show how integration of these process improvements into the purification process can facilitate debottlenecking and improve facility fit.
   Lynn Conley, Ph.D., Senior Principal Scientist, Biogen

   Mark Schofield, Ph.D., Principal R&D Engineer, Applications R&D, Pall Life Sciences

9:20 Operational Strategies and Buffer Design for Enabling Continuous/ Straight Through Downstream Processing
   Natraj Ram, Ph.D., Associate Director, Purification, Manufacturing Sciences, AbbVie Inc.

9:45 Networking Refreshment Break

Innovation at the Interfaces with R&D, The Harvest Step, and Formulations

10:15 Improved Methods for Assessing Developability of Monoclonal Antibody Candidates Prior to Purification
   Peter Tessier, Ph.D., Associate Professor, Chemical & Biological Engineering, Center for Biotechnology and Interdisciplinary Studies, Rensselaer Polytechnic Institute

10:45 Monoclonal Flocculation with Smart Polymer for Efficient Clarification of High Titer Cell and Improved Removal of Impurities
   Ken Kang, Ph.D., Principal Scientist, Head of Purification R&R, BioProcess Sciences, Eli Lilly and Company

11:15 Media Development Towards High Cell Density, High Productivity, and Low Perfusion Rates for Continuous Biomanufacturing Platforms
   The presentation will discuss our systematic approach for developing a cell culture media to support very high cell densities and high productivities while maintaining low perfusion rates for the integrated continuous biomanufacturing platform.
   Yang Yang, Ph.D., Staff Scientist I, Commercial Cell Culture Development, Sanofi

Want to earn a FREE pass to BPI? Become a Guest Blogger*.

Earn a complimentary all-access pass by serving as a Guest Blogger pre and post event. The blogger’s responsibilities will include submitting relevant content from now until the conference, attending specifically assigned sessions at the event and blogging live or same day. Plus, you will also gain exposure through our five related blogs and more than 20 LinkedIn groups.

To apply, please contact Krista Lentini at klentini@ibcusa.com or call 646-895-7316.

*For full rules and regulations, visit www.IBCLifeSciences.com/BPI
**Novel Approaches for Non-Chromatographic Purification of Proteins**

1:30 Featured Presentation

**Elastin-like Polypeptide Fusions for Purification and Delivery of Biologics**

Ashutosh Chilkoti, Ph.D., Professor and Chair, Department of Biomedical Engineering, Duke University

**A Universal Non-Affinity Purification Platform for Toxicity and Phase I Trials**

Pete Gagnon, M.S., Group Manager, Downstream Processing, Bioprocessing Technology Institute, Singapore

2:00 CMO Panel Discussion

Perspectives and Lesson Learned on Overcoming Challenges with Tech Transfers and Biomanufacturing

Moderator:

Sid Advant, Ph.D., Business Unit Head, Biologics Division, Kemwell Biopharma

Panelists:

Sandoz, Lonza, BI, Fujifilm Diosynth, KBI Biopharma

3:00 Short Break to Move to Keynote Session

**Keynote Presentations**

3:10 Chairperson’s Remarks

3:15 Innovating mAb Production to Support the Immunotherapy Revolution

A new paradigm in cancer therapy is emerging with the recent success of the antibody mediated, immune tumor killing response for melanoma. Evaluations have expanded to include a range of tumor types. In addition new alternatives and combinations are aimed at improving patient non responsiveness to PD-1. These foundational efforts of emerging cancer treatment need to be supported by agile antibody supply solutions that meet the capacity demands, while improving global access and lowering costs. Technology solutions have been implemented to speed process development and shorten the critical time to first in human clinical studies. Innovative approaches towards the ‘process of the future’ will be shown that support flexible multi product lower cost manufacturing. Continuous processing enabled by single use provides an integrated solution and the implementation challenges will be discussed.

David J. Pollard, Ph.D., Executive Director, BioProcess Development, Merck & Co. Inc.


The movement of a large portfolio, consisting of a broad spectrum of biological molecule-modalities, requires seamless integration from the research bench to the clinic. Deep alignment and partnership between the Research and the Process/Analytics functions allows for rapid and systematic product candidate screening, eliminating the most problematic candidates. Combining state-of-the-art cell lines with a regimented application of robust high-throughput process and analytical development packages enables record speeds to the first patient with minimal resources.

Spencer Fisk, Global Head, Biologics Process R&D, Novartis Pharma AG, Switzerland

4:15 Novel Approach to Developing and Producing Human Experimental Vaccines for HIV

Michael Anthony (Tony) Moody, M.D., Chief Medical Officer, Associate Professor of Pediatrics, Duke Human Vaccine Institute, Duke School of Medicine

4:45 Trick or Treat!

Halloween Reception and Exposition Hall Grand Opening

The opening night reception sponsored by Roche will feature a Halloween themed event complete with a fun and festive ambiance. Come and enjoy Halloween-inspired food, drinks, decorations and games while networking with exhibitors, poster presenters and other attendees in the exposition hall.

Sponsored by Roche

Wednesday, October 28, 2015

7:30 Registration and Coffee

7:45 Technology Workshop with Light Continental Breakfast

8:30 Chairperson’s Remarks

8:35 Amgen’s Next-Generation Biomanufacturing Facility

Kimball Hall, Vice President Manufacturing, Amgen Singapore Manufacturing Pte. Ltd.

9:15 What is the Future of Continuous Processing – What is the Time Frame for Implementing Fully Continuous Processing in Commercial Production?

Konstantin Konstantinov, Ph.D., Vice President, Technology Development, Genzyme

9:45 Networking Refreshment Break in Exposition Hall

Sponsored by Pall Life Sciences
Improvements in Rapid, High-Throughput Process Development

The Use of a Scalable High-Throughput Method to Characterize and Optimize the PEGylation of a Recombinant E.coli Derived Enzyme

High Throughput Methods to Streamline Process Development and Improve Process Understanding

Challenges and Impact of Emerging Modalities and Expression Systems on Downstream Processing

Networking Luncheon in the Exposition Hall

Networking Refreshment Break in the Exposition Hall

Advances in Host Cell Protein Identification, Understanding and Clearance

Characterization of Host-Cell Proteins Using Mass Spectrometry Enables Effective Purification Optimization

A Novel Approach to Monitor Clearance of Host Cell Proteins Associated with Monoclonal Antibodies

Identification of Individual Host Cell Proteins with Mass Spec – Top Down and Bottom Up Approaches

Recovery & Purification with the Purification of BMPs Expressed in Mammalian Systems

Bioventus LLC is developing an engineered BMP with enhanced receptor affinity optimized for increased efficacy in patients. The production of BMPs offers unique challenges not normally associated with conventional biologics such as antibodies. Challenges include the low solubility at physiological pH and a tendency to aggregate and precipitate requiring unusual conditions to stabilize the molecule throughout the production process. The presentation will focus on the development of processes to overcome production challenges unique to BMP family members.

Christopher T. Brown, M.S., Program Manager, Early Stage Protein Manufacturing, Bioventus LLC

Sponsored by PALL Life Sciences

COO, Oren E. Beske, Ph.D., Aragen Bioscience, Inc.

A Novel Approach to Monitor Clearance of Host Cell Proteins Associated with Monoclonal Antibodies

Lin Zang, Ph.D., Senior Scientist, Analytical Development, Biogen

Sponsored by MedImmune LLC

A Novel Approach to Monitor Clearance of Host Cell Proteins Associated with Monoclonal Antibodies

Min Zhu, Ph.D., Senior Scientist/Purification Process Sciences, Monoclonal Antibodies

Sponsored by MedImmune LLC

Identification of Individual Host Cell Proteins with Mass Spec – Top Down and Bottom Up Approaches

Sponsored by MedImmune LLC

Paul Brown, Ph.D., Scientist, Pfizer Inc.
5:30 **Casino Night**

Network Reception in the Exposition Hall

Feeling lucky? Wednesday night’s Networking Reception in the Exposition Hall will feature a Casino Night theme where attendees can try their luck at classic casino games like Blackjack, the Big Six Wheel, and Poker.

**Present a Poster to Showcase Your Novel Research**

Share your latest research by presenting a scientific poster during the event. All posters will be displayed in the Exposition Hall for fellow attendees to view and discuss. Poster presenters will be asked to stand by their posters during dedicated poster viewing hours to facilitate networking. All poster submissions are eligible for the Best Poster Award competition sponsored by BioProcess International Magazine. Two winning posters, one academia/industry and one supplier, will be announced live at the BPI Theater and have the opportunity to deliver an oral presentation.

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Thursday, October 29, 2015

7:00 **Bioprocess “Problem-Solving” Discussion Topics and Moderators**

These moderated discussions on a variety of bioprocess topics will allow you to share strategies and brainstorm solutions in an informal, small group setting.

- **QbD for Analytical Methods: Sharing Experiences and Approaches**
  Kazumi Kobayashi, Ph.D., Senior Principal Scientist, Technical Development, Biogen

- **Single-use and Disposable Technologies in Bioprocess Development**
  Wallace Lauzon, Ph.D., Senior Evaluator, Cytokines Division, CERB, BGTD, Health Canada

- **Regulatory Perspectives on Aging Facilities**
  Nancy Green, Ph.D., Chief, Hormones and Enzymes Division, CERB, BGTD, Health Canada

- **Inspection Trends Summary**
  Jeffrey Skene, Chief, Monoclonal Antibodies Division, CERB, BGTD, Health Canada

- **Regulatory Perspectives on CMC Submissions**
  Health Canada, Regulator TBA

- **Particulate Defects - Critical versus Minor**
  Kevin Kerls, Inspection MSAT, Hillsboro Technical Operations, Genentech, Inc. - A Member of the Roche Group

- **Opportunities and Challenges of High Concentration Biologics**
  Mark Moody, Ph.D., Chief Scientific Advisor, ReForm Biologics

- **Developability and Development: Improving the Outcome**
  Valentyn Antochshuk, Ph.D., Principal Scientist, Group Leader, Formulation Design and Process Compatibility, Merck & Co.

- **Container Closure Integrity Testing and Technology**
  Kevin M. Maloney, Ph.D., Principal Scientist, Technical Development, Biogen

- **Raw Materials Management in Biologics Production**
  Dave Kolwyck, Director, Manufacturing Sciences, Raw Material Global, Process Owner, Biogen

If you are interested in proposing or moderating a discussion topic in this breakfast session, please email at Michael Keenan mkeenan@ibcusa.com.

8:00 **Chairperson’s Remarks**

Carsten Voss, Ph.D., Applications Specialist, Process Chromatography, Bio-Rad Laboratories GmbH, Germany

**Novel Chromatography Selectivities and Innovation in Materials Science for Next Generation Purification**

Sponsored by **BIO-RAD**

8:05 **Antibody Unfolding/Aggregation on Macroporous and Polymer Grafted Cation Exchange Resins**

Giorgio Carta, Ph.D., Lawrence R. Quarles Professor, Department of Chemical Engineering, University of Virginia

8:30 **A Comparison of Multimodal Chromatographic Resins: Protein Binding and Selectivity**

Leslie Wolfe, Ph.D., Senior Scientist, Downstream Process Development, KBI Biopharma

8:55 **Novel Approaches to Modulating Product Quality of Monoclonal Antibodies**

Natraj Ram, Ph.D., Associate Director, Purification, Manufacturing Sciences, AbbVie Inc.

9:20 **Separation of IgG Glycoforms and Subclasses Using Fc Gamma Receptors as Affinity Ligands**

Austin Boesch, M.S., Co-Founder, Chief Executive Officer, Zepteon, Inc.

9:45 **Networking Refreshment Break in the Exposition Hall**

Sponsored by **PALL Life Sciences**

For more details and to submit your poster abstract, visit www.IBCLifeSciences.com/BPI.
We present a novel approach to de-risk MF scale-up through the use of process analytical technology (PAT). Chromatography based PAT was employed to improve the consistency of an MF step that had been a bottleneck in the process used to manufacture a recombinant protein. A 10 minute reverse phase ultra high performance liquid chromatography (RP-UPLC) assay was developed to provide at-line monitoring of protein concentration. The method was successfully validated and method performance was comparable to previously validated methods. The PAT tool revealed areas of divergence from a mass balance based model, highlighting specific opportunities for process improvement. Adjustment of appropriate process controls led to improved operability and significantly increased yield, providing a unique example of successful PAT deployment in the downstream purification of a recombinant protein. The general approach presented here should be broadly applicable to reduce risk during scale-up of filtration processes and should be suitable for feed-forward and feed-back process control.

Douglas Watson, Ph.D., Senior Process Engineer, Merck Manufacturing Division, Merck & Co., Inc.

A Unique Approach to Limit Aggregates in Final Purified Products

Veronique Bailly, Ph.D., Principal Scientist, BioProcess Development CMC
Team Lead, BioProcess Development CMC, Biogen

First generation legacy biologics manufacturing processes typically suffer from lack of thorough process characterization work and process understanding. The process improvement initiatives are further constrained due to the associated regulatory and validation impact of any process changes. In this work we present a case study of how the HIC capture step in a recombinant human enzyme (rEnzyme) manufacturing process was improved and optimized within the bounds of the existing regulatory filings and process definitions. The process improvements led to substantially higher step yields, debottlenecking of the manufacturing process and improvement in overall processing efficiency. Understanding the impact of chromatography resin variability on process performance was key to the success of the process improvement project. The process knowledge was established via in-house data mining and analysis, lab-scale experimentation, manufacturing investigations and discussions with the resin vendor.

Rohit Ingale, Ph.D., Process Engineer III, Manufacturing Sciences and Technology (MSAT), Genzyme, a Sanofi Company
New Paradigms in Drug Product Manufacturing

8:15 Changing the Biologics Drug Product Manufacturing Paradigm with Emerging Technologies

Internal R&D, acquisitions, biosimilars, and emerging markets are driving biotech companies to a variety of small unit volume drug products. Traditional biologics drug product mega-factories are inefficient for this changing product portfolio. We will present how emerging technologies in single-use, ready-to-use primary containers, and "adaptive" multi-container fillers can fundamentally change drug product manufacturing.

Narinder Singh, Director, Drug Product Technologies, Process Development, Amgen

8:45 Trends in Capacity Utilization in Global Fill-Finish Operations for Biologics

This presentation will provide an analysis of the current trends affecting fill and finish operations today, along with summaries of global research including percentage of usage of equipment, facilities, and staffing for vialing, pre-filled devices, and lyophilization. Based on our recent research and publications on bioprocessing fill-finish operations, and calculations of current and future trends in this operation, the presentation will quantify trends in both outsourced and in-house fill-finish. We have also focused on in-house operations, since capacity usage in this segment defines expansions in facilities, equipment and staffing. In addition, Fill-Finish CMOs derived demand is also based on whether in-house operations for Fill-Finish are being constrained by capacity crunches. The less available in-house capacity, the more likely CMO expansions will be projected.

Eric S. Langer, Managing Partner, BioPlan Associates, Inc.

9:15 Multiple Sterile Sampling of Biologics in Non-Classified Environments

Biologics formulation and filling from disposable bags currently requires complex and expensive manifolds and aseptic environment for sampling. This talk presents a proprietary Anti-Contamination Valve granted the "New Standard" label by the European NSF for a Multiple Dose Dispenser of Milk in challenging environments, with no refrigeration needed and recently used for multiple sterile sampling of an attenuated live-virus vaccine in non-classified environment, for stability and sterility evaluation.

Daniel Py, President, MedInstill Development LLC

9:45 Networking Refreshment Break

Process Analytical Technologies and QbD Applied to Drug Product Manufacturing

10:15 Emerging PAT Tools to Enable QdD Driven Control of Lyophilization Processes

Brian Wilbur, Scientist, BioTherapeutics R&D, Pfizer

10:45 Best Practices in Process Analytical Technologies Applied to Lyophilization

Uncertainty over best practices in freeze drying operations often leads to delays from lengthy internal debate over what really constitutes “best practice.” It is common that conservative positions are taken with little scientific thought. The presentation is aimed at sharing information based on engagement of academic researchers and industry partners.

Alina Alexeenko, Ph.D., Associate Professor, Purdue University
Arnab Ganguly, Ph.D., Technology Manager, IMA Life

11:15 Presentation Sponsorship Opportunity

If you have a drug product or fill-finish related case study or technology and are interested in sponsoring a presentation in this session, please contact Jennifer Wicket at jwickett@ibcusa.com or Kristen Schott at kschott@ibcusa.com

11:50 Technology Workshops

From Continuous Manufacturing Approaches for Single-Use Manufacturing

Christel Fenge, Vice President of Marketing for Fermentation, Sartorius Stedim North America

Optimal and Consistent Protein Glycosylation in Biosimilar Production

William G. Whitford, Senior Manager, Cell Culture, GE Healthcare

HPLC Fingerprinting for Efficient PAT

Ales Strancar, CEO, BIA Separations

Rapid Production of Recombinant Proteins and Stable Cell Lines at Different Scales

Weili Wang, PhD., Principal Scientist, Protein Production, MaxCyte

12:20 Luncheon Presentations

1:25 Chairperson’s Remarks

Suketu Desai, Ph.D., Vice President, Biologics Development, Drug Substance and Drug Product R&D, Allergan, Inc.

Integrating Drug Substance and Drug Product Manufacturing

1:30 Get Your Ducks in a Row-Strategies to Align Early and Late Stage Formulation Developments and Move Formulation to Fill Finish

Mark Yang, Ph.D., Director of Fill Finish Development, Late Stage Process Development, Genzyme Corp.

2:00 Streamlining Biological Drug Development to Ensure Manufacturing Continuum from Drug Substance to Drug Product: Phase-Specific Strategies to Improve Success

The presentation will provide insight and discuss aspects to consider for integration of biologics formulation development and finished drug product manufacturing with biologics drug substance development and manufacturing to have a seamless drug development. It will include process and analytical development, release, stability and manufacturing for the drug substance and formulation, analytical, aseptic manufacturing, release, stability for the finished drug product.

Suketu Desai, Ph.D., Vice President, Biologics Development, Drug Substance and Drug Product R&D, Allergan, Inc.

2:30 Technical Challenges in Moving Drug Substance to Fill/Finish

This topic will cover the various elements of the potential technical challenges being encountered starting from drug substance production through the fill / finish operation for the drug product. The topic may involve both frozen and solution drug substance forms.

Ganapathy Gopalrathnam, Senior Research Scientist, Bioproduct Pharma Design/Formulations, Eli Lilly & Company

3:00 Short Break to Move to Keynote Session
### Keynote Presentations

**Tuesday, October 27, 2015**

#### 3:10 Chairperson’s Remarks

#### 3:15 Innovating mAb Production to Support the Immunotherapy Revolution

A new paradigm in cancer therapy is emerging with the recent success of the antibody mediated, immune tumor killing response for melanoma. Evaluations have expanded to include a range of tumor types. In addition new alternatives and combinations are aimed at improving patient non responsiveness to PD-1. These foundational efforts of emerging cancer treatment need to be supported by agile antibody supply solutions that meet the capacity demands, while improving global access and lowering costs. Technology solutions have been implemented to speed process development and shorten the critical time to first in human clinical studies. Innovative approaches towards the ‘process of the future’ will be shown that support flexible multi product lower cost manufacturing. Continuous processing enabled by single use provides an integrated solution and the implementation challenges will be discussed.

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Spencer Fisk, Global Head, Biologics Process R&D, Novartis Pharma AG, Switzerland

#### 4:15 Novel Approach to Developing and Producing Human Experimental Vaccines for HIV

Michael Anthony (Tony) Moody, M.D., Chief Medical Officer, Associate Professor of Pediatrics, Duke Human Vaccine Institute, Duke School of Medicine

**Wednesday, October 28, 2015**

#### 7:30 Registration and Coffee

#### 7:45 Technology Workshop with Light Continental Breakfast

#### 8:30 Chairperson’s Remarks

**Keynote Presentations**

#### 8:35 Amgen’s Next-Generation Biomanufacturing Facility

Kimball Hall, Vice President Manufacturing, Amgen Singapore Manufacturing Pte. Ltd.

#### 9:15 What is the Future of Continuous Processing – What is the Time Frame for Implementing Fully Continuous Processing in Commercial Production?

Konstantin Konstantinov, Ph.D., Vice President, Technology Development, Genzyme

#### 9:45 Networking Refreshment Break in Exposition Hall

Sponsored by PALL Life Sciences

#### 9:45 Trick or Treat!

Halloween Reception and Exposition Hall Grand Opening

The opening night reception sponsored by Roche will feature a Halloween theme complete with a fun and festive ambiance.

Sponsored by Roche

#### 10:25 Chairperson’s Remarks

Weiqiang Cheng, Ph.D., Process/Analytical Scientist, Genzyme, a Sanofi Company

#### 10:30 Heterogeneity of Protein Environments in Frozen Solutions and in the Dried State

Freezing and freeze-drying often produces multiple populations of protein molecules, with different local environments. Such heterogeneity is commonly related to formation of ice, and includes crystalline/amorphous or amorphous/amorphous phase separation, protein sorption on surfaces, concentration gradients due to difference in the diffusion coefficients, redistribution of the charged species and electric potential on the ice/solution interface, and solution inclusions by ice crystals. Stability of a protein is directly impacted by its environment, and the shelf life would be limited by the most unstable population of protein molecules. In this talk, we will cover examples of experimentally determined heterogeneity of protein environment in frozen solutions and freeze-dried preparations, followed by a discussion of several mechanisms leading to such heterogeneity.

Dushyant Varshney, Ph.D., Director, Manufacturing Assessment, MS&T, Hospira, Inc.

#### 11:00 Biopharmaceutical Lyo Products: Scale-Up from Lab to Manufacturing

The unique challenges of freeze drying biologics will be discussed, focusing on the following considerations when transferring a laboratory-developed product to manufacturing scale: formulations, cycle optimization using design space principles and equipment capabilities.

Lisa M. Hardwick, Research Scientist, Baxter Healthcare Medical Products

#### 11:30 Impact of Hydrogen Peroxide on a Lyophilized Product during Fill Finish Processing

Filling of protein formulations is often conducted in isolators, of which the interior surface is decontaminated by vaporous hydrogen peroxide. A trace amount of residual hydrogen peroxide can be absorbed into formulations and impact drug product during filling, lyophilization and storage. A case study and mitigation strategies will be discussed.

Weiqiang Cheng, Ph.D., Process/Analytical Scientist, Genzyme, a Sanofi Company

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Biogen Development, Kevin M. Maloney, Ph.D., challenges.

filtration and filling unit operations will be presented highlighting these characterization case studies on drug product compounding, sterile evaluation prior to tech transfer to the production scale. Process characteristics on process performance demand a thorough process equipment on product quality and the impact of formulation concentration protein drug products, the impact of manufacturing challenges in aseptic fill-finish manufacturing. Compared to low

Highly concentrated, viscous protein formulations present numerous

Concentrated Protein Drug Products

Aseptic Fill-Finish Manufacturing of Highly

Aseptic Filling Processes

The case study Boehringer Ingelheim Aseptic Area 5 was a successful project of transparency, flexibility and innovative aseptic technologies in this state-of-the-art product manufacturing area. The U-shape line design provides flexible usage of individual processing steps while maximizing operational time of the area and allowing fast response to customer needs. The newly added drug product area provides best practice for aseptic processing in isolator technology. It delivers all dosage forms essential for the parenteral application of biopharmaceuticals, for example double chamber cartridges, for inhalational anthrax, and supported by federal funds from ASPR/BARDA under Contract No. HHSO100201000026C. The Anthim® aseptic filling process was transferred from a hand-filled process at a clinical CMO to a commercial CMO for optimization and validation using an automated fill line. This presentation is a case study highlighting the CMO selection strategy, and lessons learned during the evolution of the Anthim® aseptic filling process. The discussion will focus on filling process yield improvements, critical error reduction, process validation strategy, and best practices to establish a flexible, robust commercial filling process at a CMO.

Anthony Samawova, Senior Manager of Aseptic Filling Operations, Elusys Therapeutics

Aseptic Area 5 and Combi Line Project – Case Study of an Integration in an Existing Building

Additionally, the challenging project of transparency, flexibility and innovative aseptic technologies in this state-of-the-art product manufacturing area. The U-shape line design provides flexible usage of individual processing steps while maximizing operational time of the area and allowing fast response to customer needs. The newly added drug product area provides best practice for aseptic processing in isolator technology. It delivers all dosage forms essential for the parenteral application of biopharmaceuticals, for example double chamber cartridges, for inhalational anthrax, and supported by federal funds from ASPR/BARDA under Contract No. HHSO100201000026C.

Elusys Therapeutics has pioneered the development and commercial production of an anti-toxin antibody, Anthim® (obiltoxaximab), in development for the treatment and prophylaxis of inhalational anthrax disease. This product has been developed for the United States Government as a medical countermeasure for inhalational anthrax, and supported by federal funds from ASPR/BARDA under Contract No. HHSO100201000026C. The Anthim® aseptic filling process was transferred from a hand-filled process at a clinical CMO to a commercial CMO for optimization and validation using an automated fill line. This presentation is a case study highlighting the CMO selection strategy, and lessons learned during the evolution of the Anthim® aseptic filling process. The discussion will focus on filling process yield improvements, critical error reduction, process validation strategy, and best practices to establish a flexible, robust commercial filling process at a CMO.

Anthony Samawova, Senior Manager of Aseptic Filling Operations, Elusys Therapeutics

2:45 CMO Selection Strategy, Process Optimization, and Validation of the Anthim® Aseptic Filling Process

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Anthony Samawova, Senior Manager of Aseptic Filling Operations, Elusys Therapeutics

Aseptic Filling Processes

Highly concentrated, viscous protein formulations present numerous challenges in aseptic fill-finish manufacturing. Compared to low concentration protein drug products, the impact of manufacturing equipment on product quality and the impact of formulation characteristics on process performance demand a thorough process evaluation prior to tech transfer to the production scale. Process characterization case studies on drug product compounding, sterile filtration and filling unit operations will be presented highlighting these challenges.

Kevin M. Maloney, Ph.D., Principal Scientist, Technical Development, Biogen

Aseptic Fill-Finish Manufacturing of Highly Concentrated Protein Drug Products

Highly concentrated, viscous protein formulations present numerous challenges in aseptic fill-finish manufacturing. Compared to low concentration protein drug products, the impact of manufacturing equipment on product quality and the impact of formulation characteristics on process performance demand a thorough process evaluation prior to tech transfer to the production scale. Process characterization case studies on drug product compounding, sterile filtration and filling unit operations will be presented highlighting these challenges.

Kevin M. Maloney, Ph.D., Principal Scientist, Technical Development, Biogen

Networking Luncheon in the Exposition Hall

Chairperson’s Remarks

Kevin M. Maloney, Ph.D., Principal Scientist, Technical Development, Biogen

New Strategies and Technologies in Aseptic Filling Processes

Networking Refreshment Break in the Exposition Hall

Sponsored by PALL Life Sciences

Casino Night

Feeling lucky? Wednesday night’s Networking Reception in the Exposition Hall will feature a Casino Night theme where attendees can try their luck at classic casino games like Blackjack, the Big Six Wheel, and Poker.

Co-Sponsored by BIO-RAD and Life Sciences at Infotemia Business
Thursday, October 29, 2015

Bioprocess “Problem-Solving” Discussion Topics and Moderators

These moderated discussions on a variety of bioprocess topics will allow you to share strategies and brainstorm solutions in an informal, small group setting.

QbD for Analytical Methods: Sharing Experiences and Approaches
Kazumi Kobayashi, Ph.D., Senior Principal Scientist, Technical Development, Biogen

Single-use and Disposable Technologies in Bioprocess Development
Wallace Lauzon, Ph.D., Senior Evaluator, Cytokines Division, CERB, BGTD, Health Canada

Regulatory Perspectives on Aging Facilities
Nancy Green, Ph.D., Chief, Hormones and Enzymes Division, CERB, BGTD, Health Canada

Inspection Trends Summary
Jeffrey Skene, Chief, Monoclonal Antibodies Division, CERB, BGTD, Health Canada

Regulatory Perspectives on CMC Submissions
Health Canada Regulator TBA

Particulate Defects - Critical versus Minor
Kevin Kerls, Inspection MSAT, Hillsboro Technical Operations, Genentech, Inc. - A Member of the Roche Group

Opportunities and Challenges of High Concentration Biologics
Mark Moody, Ph.D., Chief Scientific Advisor, ReForm Biologics

Developability and Development: Improving the Outcome
Valentyn Antochshuk, Ph.D., Principal Scientist, Group Leader, Formulation Design and Process Compatibility, Merck & Co.

Container Closure Integrity Testing and Technology
Kevin M. Maloney, Ph.D., Principal Scientist, Technical Development, Biogen

Raw Materials Management in Biologics Production
Dave Kolvyck, Director, Manufacturing Sciences, Raw Material Global, Process Owner, Biogen

If you are interested in proposing or moderating a discussion topic in this breakfast session, please email at Michael Keenan mkeenan@ibcusa.com.

8:00 Chairperson’s Remarks
Donald Singer, Quality Manager, Microbiology, R&D, GlaxoSmithKline

Drug Product Case Studies: Visual Inspections, Combination Products and Viscosity Challenges

8:15 Impact of Inspector Training on Visual Inspection Process Capability
In 2012, Roche implemented a new corporate standard for visual inspection processes, including inspector qualification requirements. This new standard required changes to local procedures for visual inspector qualification and training. These changes resulted in a significant change in the site’s detection capability for particulate defects in liquid solution. The presentation will describe the changes, the impact to detection capability, impact to the manufacturing process, and lessons learned regarding managing changes to visual inspection processes.

Kevin Kerls, Inspection MSAT, Hillsboro Technical Operations, Genentech, Inc. - A Member of the Roche Group

8:45 Combination Product Development – Drug Product Development and Fill-finish Challenges and Strategies
Sujit Basu, Ph.D., Head, Drug and Combination Products, Shire

9:15 Viscosity As a Design Criteria for Drug Product Formulations
Dosing of monoclonal antibodies less than 1.5mL total volume in devices often entails targeting high concentrations, sometimes with unexpected self-association increasing viscosity. Unexpected self-association can result in high viscosity which has an impact on fill-finish operations. The fill finish unit operations and delivery device will dictate the upper limit of viscosity that fits into an existing manufacturing line. Typical viscosity operating limits will be shown from review of fill-finish unit operations with the impact on inspection of biologics highlighted. From this information the working design space can be defined for a filling line and used in formulation selection.

Deborah Shnek, Ph.D., Process Development Director, Drug Product Development LLC

9:45 Networking Refreshment Break in the Exposition Hall

Sponsored by PALL Life Sciences

Drug Product Case Studies: Filling Technologies

10:30 Measuring Hydrogen Peroxide Residuals and Product Exposure on Isolator and RABS Filling Lines
This presentation will describe how residual hydrogen peroxide from isolator or RABS decontamination cycles is taken up into liquid drug product during filling. This uptake process is not limited to atmospheric peroxide, and requires adequate measurement and mitigation to prevent product quality impact. Data will be presented from both commercial-scale case studies and lab work.

Aaron Hubbard, Engineer 1, Pharmaceutical Processing & Technology Development, Genentech

11:00 Single-Use: Adding Flexibility to Fill Finish
Whether you have a product early in its life cycle and you are trying to build a facility that will meet the forecasted sales, or you have a mature product that is experiencing declining sales but still crowding your facility schedule, Single Use could be a solution to make your facility more flexible in batch sizes, speed of change overs, optimum runs, etc. Do you have an ‘Aging’ facility that is beginning to raise concerns about risk to the patient, perhaps the containment properties of Single Use Systems would be the injection of the right technology to give new life to that facility.

Christopher Smalley, Ph.D., Director, Engineering, Global Technical Operations, Merck & Co.

11:30 Compliant Portable Filling of Biologics in Non-Classified Environments

Biologics manufacturing has been shifting away from large-scale centralized to smaller-scale localized operations due to contemporary political and commercial incentives. Huge immovable capital, and employee aseptic training and retention have been impediments for traditional aseptic fill-finish operations. This talk presents a proprietary 21 CFR 211 compliant technology enabling sterile transfers in non-classified environments, and discusses evaluation of the technology in localized portable manufacturing of an attenuated live-virus vaccine.

Debashis Sahoo, Director, Engineering, MedInstill Development LLC

12:05 Technology Workshops
Have Your Presentation Included Here!
Contact Jennifer Wickett (companies A-L) at jwickett@ibcusa.com or Kristen Schott (companies M-Z) at kschott@ibcusa.com for details.

12:35 Networking Luncheon and Last Chance for Exposition Hall Viewing
Formulation Strategies for Biotherapeutics

Opportunities and Challenges of High Concentration Biologics: Case Studies

The development of high concentration biologic formulations allows for decreasing the injection volume which can increase patient comfort and convenience. For some mAbs, a high concentration formulation could permit a change in the route of administration from i.v. to s.c., which can lead to the drug’s use in new clinical settings and indications. In spite of the high value of improved formulations, the industry has seen few advances for high concentration biologics and formulation scientists continue to be faced with challenges of poor stability and high viscosity which limit concentration. ReForm will present case studies on the successful development of low viscosity, high concentration biologics.

Mark Moody, Ph.D., Chief Scientific Advisor, ReForm Biologics

Connecting Developability and Formulation Development

The developability concept encompasses protein design, expression, purification, formulation and analytical attributes. Thorough understanding of the biophysical and biochemical properties of the molecule is critical to program de-risking and successful pharmaceutical development. The connection between developability and formulation development is further explored with practical examples.

Valentyn Antochshuk, Ph.D., Principal Scientist, Group Leader, Formulation Design and Process Compatibility, Merck & Co.

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- Benefit from face-to-face time with new technology companies to learn about tools and streamline your bioprocesses
- Form collaborations and alliances to share the same goals of propelling the bioprocessing industry towards new heights of clinical and commercial success

Information on how to access the application will be emailed to all attendees starting in August 2015. If you registered for the event and do not receive your login information by end of August 2015, contact Howie Choi at hchoi@ibcusai.com.

*Attendees with a 2, 3 or 4-day pass

Thursday, October 29, 2015 (continued)

1:55 Chairperson’s Remarks
Sigma S. Mostafa, Ph.D., Director, Process Development, KBI Biopharma Inc.

Innovation at the Interface with Formulations

2:00 Impact of Ion-mAb Interactions on the UFDF Process: Towards Process and Product Design
Diane D. Dong, Ph.D., Principal Scientist, Manufacturing Sciences, AbbVie

2:30 Challenges of High Concentration Formulations - Dealing with Viscosity and Excipients
Pfizer Representative Invited

3:00 Networking Refreshment Break

3:30 Formulation Strategies for Biotherapeutics

3:40 Opportunities and Challenges of High Concentration Biologics: Case Studies

3:50 Connecting Developability and Formulation Development

4:00 CHO Host Cell Proteins and Impacts on Product Formulation

This presentation will discuss an application of genomics and proteomics related to CHO host cell proteins (HCPs). In particular, certain difficult to remove HCPs, identified by proteomics, appear to have an impact on product quality in the context of formulation. We hypothesize that the presence of a specific HCP in polysorbate-containing drug formulations may result in increased degradation rates of polysorbates and discuss our findings related to this hypothesis.

Kelvin H. Lee, Ph.D., Gore Professor of Chemical & Biomolecular Engineering and Director, Delaware Biotechnology Institute, University of Delaware

4:30 Close of Conference
**Manufacturing Strategy**

**Tuesday, October 27, 2015**

7:00  *Registration and Coffee*

8:00  **Chairperson's Remarks**
Richard Reineke, Director, Upstream Manufacturing, Amgen, Inc.

**Strategies to Ensure Manufacturing Efficiency and Quality**

8:15  **A Holistic Approach to Developing a Robust Drug Product Manufacturing Process that Ensures Consistent Product Quality Attributes**
Ganapathy Gopalrathnam, Senior Research Scientist, Bioproduct Pharma Design/Formulations, Eli Lilly & Company

8:45  **A Successful Lean Manufacturing System in a Biologics Manufacturing Plant**
Can biologics DS supply be reliable and cost-reduced? Do operators connect daily performance to quality and cost? Are new product introductions too slow? A successful lean manufacturing system at Amgen Rhode Island has decreased cost, reduced errors and increased speed. New daily practices have reduced scrap, increased reliability and improved yields. Well-trained operators, purposeful presence and a safety-first culture have decreased non-conformances and improved new product introductions.
Richard Reineke, Director, Upstream Manufacturing, Amgen, Inc.

9:15  **A Life Cycle Approach to Managing Risk throughout the Design, Qualification, and Operation of Manufacturing Systems**
Risk management is most effective when used prospectively during product development and process design, when design and control systems are easily modified to reduce risk and improve product quality. Building quality into drug product manufacturing processes up front is better than testing these products for defects later. The use of risk management to design, qualify, and operate systems used in manufacturing processes is beneficial.
Ghada Haddad, Director, Engineering, Sterile & Validation CoE, Merck & Co.

9:45  **Networking Refreshment Break**

10:00  **New Concepts in Facility Design and Biotherapeutic Production**

10:15  **Process Simulation and Facility Modeling: Identification of Increased Throughput Enabling Projects in a Complex Multiproduct Manufacturing Environment**
Biogen's portfolio of drug substance process/facility models is used to analyze multi-product manufacturing scenarios. Models are leveraged to identify potential capital projects that can directly increase facility throughput and quantify relative impact of competing projects (i.e. reductions in product changeover time vs. reductions in batch to batch turnaround times).
Suzanne Stuhler, Senior Process Engineer, Operations Technology & Innovation, Biogen

10:45  **The Automated Swiss Large Scale Biologics Manufacturing Facility**
Dominik Wegmann, Ph.D., Head of Manufacturing Science & Technology, Biological Production, Lonza AG, Switzerland

11:15  **Therapeutic Protein Production On-Demand**
In a paradigm shift from the conventional large scale therapeutic protein manufacture at a site distant from the end user, our team has been developing a compact, agile platform designed to produce therapeutic proteins at the point-of-care. In this presentation, we will describe our progress towards making a briefcase size device that will serve as the factory of the future and enable biologics production on-demand at the point-of-care. Our core technology uses a novel CHO cell extract for in vitro expression of virtually any protein and couples it with a simple, single step intein-based purification system that has the potential of producing a therapeutic ready for delivery to the patient. This entire device and process are being robustly validated by analytics and regulatory teams. Case studies based on the production of Streptokinase and Erythropoietin will be demonstrated.
Govind Rao, Ph.D., Professor and Director, Center for Advanced Sensor Technology, University of Maryland, Baltimore County

11:50  **Technology Workshops**

**From Continuous Manufacturing Approaches for Single-Use Manufacturing**
Christel Fenge, Vice President of Marketing for Fermentation, Sartorius Stedim North America

**Optimal and Consistent Protein Glycosylation in Biosimilar Production**
William G. Whitford, Senior Manager, Cell Culture, GE Healthcare

**HPLC Fingerprinting for Efficient PAT**
Ales Strancar, CEO, BIA Separations

**Rapid Production of Recombinant Proteins and Stable Cell Lines at Different Scales**
Weili Wang, PhD., Principal Scientist, Protein Production, MaxCyte

12:20  **Luncheon Presentations**
This document contains a summary of presentations from a conference on biomanufacturing. The summaries are too long to be included here, but they discuss topics such as the production of monoclonal antibodies, continuous biomanufacturing, and the future of antibody production. The conference includes presentations on the development of a phase III cell culture process for an IgG4 antibody, a flexible platform for the manufacture of stable and unstable therapeutic agents, and the use of membrane absorbers to enable the use of single use processes. The presentations also cover the future of continuous processing, innovative process development strategies, and manufacturing strategies. The conference is sponsored by Roche and Pal Life Sciences.
11:40 Solving the Genealogy Puzzle in Biologics Manufacturing
Dave Kolwyck, Director, Manufacturing Sciences, Biogen

Data is being generated at all steps of biologics manufacturing from raw material suppliers through finished goods - but splits and joins in the process genealogy add tremendous complexity, which needs to be overcome in order to leverage all the data available. How can Data Science can help?

Gabe Josset, Senior Associate Scientist, Process Informatics, Biogen

12:05 Technology Workshops

Using Process and Activity to Drive Clone Selection
Oren E. Beske, Ph.D., COO, Aragen Biosciences, Inc

Single-Use Fermentation: Understanding Process Economy and Process Performance
Kenneth Clapp, Senior Global Product Manager, Bioreactors, GE Healthcare

An Insight into Recent Developments in Protein A Chromatography
Jonathan Royce, Senior Product Manager, Bioprocess Product Marketing – Downstream, GE Healthcare

12:35 Networking Luncheon in the Exposition Hall

1:40 Chairperson’s Remarks
Tony White, Director, BioPhorum Operations Group (BPOG), United Kingdom

Continued Process Verification Strategies for Biologics

1:45 Condensed Playbook for Continued Process Verification (CPV)

Following the well-received publication of the BioPhorum Operations Group’s (BPOG) CPV Case Study, the BPOG CPV team has created a ‘playbook’ or step-by-step guide to the implementation of CPV in table form. The guide aligns with the FDA’s product lifecycle model and refers to a flow diagram. The aim is to make implementing CPV an activity that is accessible to everyone in the Biopharmaceutical Operations environment. This presentation will describe the playbook, and how to access and use it.

Marcus Boyer, Ph.D., Associate Director of Process Life-cycle Management, Bristol-Myers Squibb

2:15 Continued Process Verification (CPV) Informatics Systems and Validation

Fundamentally, the purpose of informatics system validation is to ensure a sufficient level of data integrity. In the case of Continued Process Verification (CPV), validation is complicated by the need to pull data from a number of source systems. The CPV Informatics system is essentially one that enacts data gathering processes and it is essential that the governance models for source systems are understood when the CPV system is set up. Validating efficiently, through risk assessment and justified approaches is essential, given the potentially massive informatics testing requirements for activities like CPV. Useful approaches will be highlighted in this presentation. It needs to be recognized that a CPV Informatics system will be subjected to changes after it has been released for use, and means of managing change will be part of this presentation.

Carly Cox, Senior Process Engineer, Pfizer

2:45 Implementing Continued Process Verification (CPV) for Legacy Products

In 2014, the BioPhorum Operations Group published the CPV Case Study, detailing how CPV plans can be created, with a focus on new products. Subsequently, the BPOG CPV team has considered the case of legacy products and this presentation covers their findings. It will include: the gathering and use of existing manufacturing data, the discovery of previous trends and management across multiple sites amongst other topics.

Bert Frohlich, Ph.D., Director, Process Controls and Quality by Design, Manufacturing Sciences & Technology, Shire

3:15 Networking Refreshment Break in the Exposition Hall

Sponsored by Pall Life Sciences

For up-to-date program information and new abstracts, visit: www.IBCLifeSciences.com/BPI
Thursday, October 29 • 4:00 pm pickup time • Destination is Marlborough, MA

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Contact Jennifer Wickett: (508) 614-1672 • jwickett@ibcusa.com
**Manufacturing Strategy**

**Thursday, October 29, 2015** (continued)

8:00 Chairperson’s Remarks  
Lisa Bradbury, Ph.D., Director, Pall Corporation

**Closed System Manufacturing**

8:15 ADC Production: Integration of the Conjugation Step in a Standard Protein Plant Using Closed Systems  
ADC manufacturing in most cases uses 2 separate facilities for production, a protein plant with its typical segregation and a special toxin conjugation facility to produce the ADC drug substance. This talk will describe a set-up to do the toxin conjugation within the footprint of a downstream suite of a standard protein plant. The prerequisites to achieve that such as closed systems operation, using disposables as well as isolator technology for the conjugation part will be described in detail.  
Berthold Boedeker, Ph.D., Chief Scientist, Global Biologics, Biotech Development, Bayer Pharma AG, Germany

8:45 Closed Processing and Sanitizing Temporary Openings  
Closed processing in controlled, non-classified spaces mitigates risks associated with contaminants in the manufacturing environment whilst improving quality. Significant benefits can be gained in simplified facility designs and low levels of environmental control. However, advances in closed processing technology have not completely eliminated the need to temporarily open systems and it is impractical to use typical procedures for closure. To address this issue, the Biophorum Operations Group (BPOG) have collaborated with the Biotechnology Training and Education Centre (BTEC) to establish whether liquid sanitization can be used to effectively close a temporary opening in an otherwise closed system. A series of tests have been undertaken, using equipment that closely models real processing conditions. This presentation will report on these tests.  
Kavita Ramalingam Iyer, Senior Process Scientist, Merck, Inc.

9:15 Presentation Sponsorship Opportunity  
If you have a manufacturing related case study or technology and are interested in sponsoring a presentation in this session, please contact Jennifer Wicket at jwickett@ibcusa.com or Kristen Schott at kschott@ibcusa.com

9:45 Networking Refreshment Break in the Exposition Hall  
Sponsored by Pall Life Sciences

10:30 Design of a Clinical Manufacturing Facility Strategically Aligning Single-use and Fixed Equipment  
The presentation will describe the design of a biologics clinical manufacturing facility that integrates single-use and stainless steel equipment strategically to take advantage of the strengths of both. Single-use bioreactors provide several advantages. Among them are: (1) Less capital and validation investments, (2) Flexibility, and (3) Quicker turnaround between batches. Single-use mixing systems provide similar advantages in terms of the initial capital layout and turnaround times. The facility will integrate single-use bioreactor and mixing systems with conventional stainless steel centrifuge and chromatography skids to take advantage of the latest technological advancements. The presentation will also describe the design philosophy for the facility incorporating optimum process, material and personnel flow as well as area classifications meeting the latest compliance requirements.  
Sourav Kundu, Ph.D., Director, Biopharmaceutical Development, Teva Biopharmaceutical, USA

11:00 Considerations for Technology Transfer from Single-use to Stainless  
Single-use manufacturing has been increasingly implemented in the recent years in the biotech industry for early phase clinical production. As programs advance, larger volume production is needed and traditional stainless technology is used. We will review considerations for technology transfer from single-use to stainless technology.  
Anna Pisania, Ph.D., Staff Engineer, Acceleron

11:30 Implementing Flexible Manufacturing & Single-Use Systems in Upstream Processing  
Speaker TBA

12:05 Technology Workshops  
**Have Your Presentation Included Here!**  
Contact Jennifer Wickett (companies A-L) at jwickett@ibcusa.com or Kristen Schott (companies M-Z) at kschott@ibcusa.com for details.

12:35 Networking Luncheon and Last Chance for Exposition Hall Viewing

1:55 Introduction of Groups, Members and Status of Collaborations  
Tony White, Director, BioPhorum Operations Group (BPOG)  
Kevin Ott, Executive Director, Bio-Process Systems Alliance (BPSA)

**Single-Use Technologies and Applications: A Coordinated View from Industry Consortia**

2:10 Change Notification Allied Efforts  
BPOG and BPSA Speakers TBA

2:35 User Requirements: A User Perspective  
BPOG Speaker TBA

3:00 Networking Refreshment Break

**Single-Use Technologies and Applications: A Coordinated View from Industry Consortia**

3:30 Extractables Test Methods: Progress Towards a Standard  
BPOG and BPSA Speakers TBA

3:45 BPSA’s 2015 Single-Use Quality Test Matrices Guide  
BPSA Speaker TBA

4:15 NEW! Town Hall Forum Discussion  
**Single-Use Standardization: Progress in Improved Alignment of Guidelines**  
Moderator: James Dean Vogel, Founder and Director, The BioProcess Institute  
**BPOG Perspective:** Tony White, Director, BioPhorum Operations Group  
**BPSA Perspective:** James Dean Vogel, Founder and Director, The BioProcess Institute  
**PDA Perspective:** Robert Repetto, Senior Director, External Affairs, Pfizer  
**ASTM Perspective:** Robert Steininger II, ASTM SubCommittee Chairman, Biotechnology and Consultant, BioPE, LLC  
**ASME/BPE Perspective:** Jay Ankers, Director of Technology, M+W Group

5:00 Close of Conference

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Analytical, Formulation and Quality

Tuesday, October 27, 2015

7:00 Registration and Coffee

8:00 Chairperson’s Remarks
Johnson Varghese, Ph.D., Senior Director/Head, Analytical Development, Shire

Linking Analytics with Critical Quality Attributes and Multi-Attribute Monitoring and Control

8:05 Critical Quality Attribute (CQA) Assessment – From Theory to Practice!
CQA assessment as part of QbD submissions is getting applied to more and more development projects in the pharmaceutical industry. Concepts and strategies for CQA assessment have been developed and shared in recent years. This talk will provide some practical guidance on CQA assessment based on a case study: What are the work packages, which experiments should be done and how, which functions have to be involved, which documents have to be created? Marco Thomann, Ph.D., Group Leader, Development Analytics, Roche Diagnostics GmbH, Germany

8:30 High Throughput Determination of Critical Quality Attributes for Rapid Process Development
A high-throughput platform assay has been developed and automated for the determination of critical quality attributes of monoclonal antibodies in conditioned medium. Conditioned media samples containing monoclonal antibodies were purified and analyzed for critical quality attributes. Data quality and efficiency outcome will be presented.
Veera Padmanabhan, Ph.D., Director, R&D, MedImmune – A member of the AstraZeneca Group

8:55 Applying Quality-by-Design to Viral Biopharmaceuticals & Vaccines: Highlights, Lessons Learned & Observations Involving a Seasonal Vaccine
Michael Washabaugh, Ph.D., Senior Director, Biopharmaceutical Development, MedImmune – A member of the AstraZeneca Group

9:20 Implementing Multi-Attribute LC/MS Methods for More Informed Process Development
Multi-attribute LC/MS peptide mapping provides comprehensive characterization and quantitation of protein post-translational modifications and impurities. Recent software advances have facilitated the routine application of this technology, enabling more informed decision making throughout process development. Case studies will demonstrate the implementation of multi-attribute LC/MS during different stages of development.
Matthew Taylor, Analytical Scientist, Process Development, Shire

9:45 Networking Refreshment Break

10:05 Application of Analytical Techniques for Product Quality Driven Process Development and Routine cGMP Manufacturing
The presentation will discuss using analytical methods to optimize expression of proteins with specific qualities or properties, and the utilization of rapid methods during clone selection, cell culture, recovery and purification development. These methods are then directly adapted to routine manufacturing testing thereby ensuring consistent analytical data throughout the clinical development lifecycle.
Greg W. Adams, Ph.D., Director Analytical Development, Fujifilm Diosynth Biotechnologies

10:15 High Throughput Analytical Assays by Octet to Support Phase II/III Monoclonal Antibody Manufacturing and Drug Product Release and Stability
Potency is an important quality attribute in monoclonal antibody manufacturing and quality control. When we began FDA-approved Pivotal Phase III clinical trial for Cachexia, we developed an innovative high-throughput kinetics assay using ForteBio Octet RED96 to accommodate the significantly increased testing volume due to manufacturing scale-up. Validation of this new method showed a precision of <17%, and it is also specific, accurate and robust to use as a QC drug release and stability assay. The number of samples one operator can test per day using the new Octet method is significantly increased (8-fold) compared to the Biacore assay used to be used in Phase I. Besides binding kinetics assay, we also use Octet RED96 to monitor cell culture titer in Manufacturing, which is also a validated QC assay, and deliver results in 1 hr.
Qian Wu, Ph.D., Director of Quality Control, XBiotech USA, Inc.

10:45 A Platform Approach to Support Development and Lot-release Testing of VLP-based Vaccines
Togaviridae alphaviruses Chikungunya and Western, Eastern, and Venezuelan Equine Encephalitis demonstrate high infectivity, multiple neurological morbidities, and varying mortalities. Although complex, multicomponent enveloped VLP vaccines generated for these viruses present characterization and release assay challenges, efficacious platform assays for content, potency, and purity have been developed that require minimal assay modification among VLPs to successfully support Phase I clinical studies.
Jonathan W. Cooper, Ph.D., Staff Scientist, Analytical Development, Vaccine Production Program, Vaccine Research Center, NIAID/NIH

11:05 High Throughput Analytical Methods for Quality Control

11:30 Quality by Design in Biosimilar Development: Enhanced Process Knowledge for Targeting Product Quality
The present case study established the foundations of an enhanced QbD approach in a CHO process producing a biosimilar mAb. Based on unique characteristics of biosimilar development, tailored risk management tools were used to map interactions between process parameters and product quality. Thereby, cell physiology was identified as an important cluster of critical process variables. In order to gain physiological knowledge, the fed-batch mAb process was characterized and two major phases were identified. Whereas the excess of nutrients led to overflow metabolism in the first phase, the second phase was characterized by nutrient limitations. Two multivariate experimental designs were subsequently conducted in order to investigate the effect of process parameters on cell physiology and product quality in both process phases. The generated physiological knowledge triggered the development of process control strategies to decrease overflow metabolism in the first phase, and maximize product yield and adjust product quality in the second phase of the process.
Dénes Zalai, Ph.D. Candidate, Vienna University of Technology, Austria

11:50 Luncheon Presentations

12:20 Luncheon Presentations

1:25 Chairperson’s Remarks
Rustom S. Mody, Ph.D., Head of R&D (Biotech Division), Lupin Limited, India

Biosimilar Product Quality, Characterization and Comparability

1:30 Quality by Design in Biosimilar Development: Enhanced Process Knowledge for Targeting Product Quality

For up-to-date program information and new abstracts, visit: www.IBCLifeSciences.com/BPI
Analytical, Formulation and Quality

Tuesday, October 27, 2015 (continued)

2:00 High-throughput Analytical Systems for Biosimilar Process Development, Characterization and Comparability
Biosimilar companies are trying to develop biosimilars at a break-neck speed. It is well recognized that “Process is the Product.” Upstream cell culture process parameters are key drivers in determining molecular similarity to the reference drug. Therefore optimization of these parameters must be done with a close watch on structural similarity to the reference drug. With the advent of microbioeactors, a high throughput system for optimizing the cell culture processes is now available. Such progress needs to be matched by a high throughput downstream processing along with high throughput in-process analytical capability. The talk focuses on the emergence of various high throughput analytical techniques that can provide speedy analysis of the molecular structure, heterogeneity, higher order structure, quality attributes, and functional behavior of biosimilar product made under numerous process conditions which can eventually speed up the development of biosimilars.
Rustom S. Mody, Ph.D., Head of R&D (Biotech Division), Lupin Limited, India

2:30 Characterization and Quantitative Comparison of Remicade® and its Biosimilar Remsima™
Remsima™ is a mimic of an eight billion dollar product Remicade® and the first mAb biosimilar approved in Europe and Canada. We compared multiple lots of Remsima™ and Remicade® by complete proteomic analysis of digested proteins by LC-MS coupled with powerful statistical software. Samples were quantitatively compared according to levels of oxidation, deamidation, terminal lysine truncation, glycation, glycosylation, disulfide bond formation, sequence variance and host cell proteins. Whereas the products appeared to be highly similar for most of the parameters tested, the levels of glycation was significantly higher for Remsima™ relative to Remicade®. Increased hydrophobicity in the biosimilar was confirmed by reduced retention times of IdeS digests by RP-HPLC. Increased glycation could reasonably be responsible for reduced binding to Fc-gamma receptor and, potentially even, reduced efficacy in treatment of inflammatory bowel disease. Hence, the proteomic analysis described here may be useful for detailed comparative structural characterization of pharmaceutical proteins.
Anna Schwendeman, Ph.D., Assistant Professor, Medicinal Chemistry, University of Michigan

2:00 Short Break to Move to Keynote Session

Keynote Presentations

3:10 Chairperson’s Remarks

3:15 Innovating mAb Production to Support the Immunotherapy Revolution
A new paradigm in cancer therapy is emerging with the recent success of the antibody mediated, immune tumor killing response for melanoma. Evaluations have expanded to include a range of tumor types. In addition new alternatives and combinations are aimed at improving patient non responsiveness to PD-1. These foundational efforts of emerging cancer treatment need to be supported by agile antibody supply solutions that meet the capacity demands, while improving global access and lowering costs. Technology solutions have been implemented to speed process development and shorten the critical time to first in human clinical studies. Innovative approaches towards the ‘process of the future’ will be shown that support flexible multi product lower cost manufacturing. Continuous processing enabled by single use provides an integrated solution and the implementation challenges will be discussed.
David J. Pollard, Ph.D., Executive Director, BioProcess Development, Merck & Co. Inc.

The movement of a large portfolio, consisting of a broad spectrum of biological molecule-modalities, requires seamless integration from the research bench to the clinic. Deep alignment and partnership between the Research and the Process/Analytics functions allows for rapid and systematic product candidate screening, eliminating the most problematic candidates. Combining state-of-the-art cell lines with a regented application of robust high-throughput process and analytical development packages enables record speeds to the first patient with minimal resources.
Spencer Fisk, Global Head, Biologics Process R&D, Novartis Pharma AG, Switzerland

4:15 Novel Approach to Developing and Producing Human Experimental Vaccines for HIV
Michael Anthony (Tony) Moody, M.D., Chief Medical Officer, Associate Professor of Pediatrics, Duke Human Vaccine Institute, Duke School of Medicine

4:45 Trick or Treat!
Halloween Reception and Exposition Hall Grand Opening
The opening night reception sponsored by Roche will feature a Halloween theme complete with a fun and festive ambiance.
Analytical, Formulation and Quality

**Wednesday, October 28, 2015 (continued)**

**10:55** Importing Best Practice into Raw Material Change Notification
The way raw material change notifications are communicated in the biopharmaceutical industry often causes anguish and significant extra work for both suppliers and end users. Often, changes take too long to assess and there is a growing consensus that greater clarity and guidance would be beneficial on both the type of changes requiring advanced notice and the information needed for impact and risk assessment. A group of BPOG member companies are working together and with suppliers to develop such guidance. As part of this study they have reviewed the change notification solutions used in the aerospace, automotive and semi-conductor industries with the intention of importing best practice. This presentation will outline the team’s work and their plans on this common challenge for us all.

Shamini Nathen, Senior Quality Engineer, Bristol Myers Squibb

**11:20** Innovation Development within a Strategic Supplier Program
The biopharmaceutical industry is developing increasingly stringent demands on the quality and consistency of the raw materials used in their manufacturing. To manage this complexity, many large pharmaceutical organizations are creating strategic supplier relationship programs to focus their development activities. This presentation will discuss strategies to manage a strategic supplier innovation pipeline that preserves the freedom to operate for both organizations and creates valuable solutions which can be broadly disseminated across the industry.

Dave Kolwyck, Director, Manufacturing Sciences, Raw Material Global Process Owner, Biogen

**11:40** Solving the Genealogy Puzzle in Biologics Manufacturing
Data is being generated at all steps of biologics manufacturing from raw material suppliers through finished goods - but splits and joins in the process genealogy add tremendous complexity, which needs to be overcome in order to leverage all the data available. How can Data Science can help?

Gabe Josset, Senior Associate Scientist, Process Informatics, Biogen

**12:05** Technology Workshops

**Aragen**

*Using Process and Activity to Drive Clone Selection*
Oren E. Beske, Ph.D., COO, Aragen Bioscience, Inc

*Single-Use Fermentation: Understanding Process Economy and Process Performance*
Kenneth Clapp, Senior Global Product Manager, Bioreactors, GE Healthcare

*An Insight into Recent Developments in Protein A Chromatography*
Jonathan Royce, Senior Product Manager, Bioprocess Product Marketing – Downstream, GE Healthcare

**12:35** Networking Luncheon in the Exposition Hall

**1:40** Chairperson’s Remarks
Tony White, Director, BioPhorum Operations Group (BPOG), United Kingdom

Continued Process Verification Strategies for Biologics

**1:45** Condensed Playbook for Continued Process Verification (CPV)
Following the well-received publication of the BioPhorum Operation Group’s (BPOG) CPV Case Study, the BPOG CPV team has created a ‘playbook’ or step-by-step guide to the implementation of CPV in table form. The guide aligns with the FDA’s product lifecycle model and refers to a flow diagram. The aim is to make implementing CPV an activity that is accessible to everyone in the Biopharmaceutical Operations environment. This presentation will describe the playbook, and how to access and use it.

Marcus Boyer, Ph.D., Associate Director of Process Life-cycle Management, Bristol-Myers Squibb

**2:15** Continued Process Verification (CPV) Informatics Systems and Validation
Fundamentally, the purpose of informatics system validation is to ensure a sufficient level of data integrity. In the case of Continued Process Verification (CPV), validation is complicated by the need to pull data from a number of source systems. The CPV Informatics system is essentially one that enacts data gathering processes and it is essential that the governance models for source systems are understood when the CPV system is set up. Validating efficiently, through risk assessment and justified approaches is essential, given the potentially massive informatics testing requirements for activities like CPV. Useful approaches will be highlighted in this presentation. It needs to be recognized that a CPV Informatics system will be subjected to changes after it has been released for use, and means of managing change will be part of this presentation.

Carly Cox, Senior Process Engineer, Pfizer

**2:45** Implementing Continued Process Verification (CPV) for Legacy Products
In 2014, the BioPhorum Operations Group published the CPV Case Study, detailing how CPV plans can be created, with a focus on new products. Subsequently, the BPOG CPV team has considered the case of legacy products and this presentation covers their findings. It will include: the gathering and use of existing manufacturing data, the discovery of previous trends and management across multiple sites amongst other topics.

Bert Frohlich, Ph.D., Director, Process Controls and Quality by Design, Manufacturing Sciences & Technology, Shire

**3:15** Networking Refreshment Break in the Exposition Hall
Sponsored by **PALL** Life Sciences

**3:45** Manufacturing Strategies for Legacy Products

**4:00** Building a Process Improvement Strategy for a Legacy Biologics Process Which Enables Implementation of a Next Generation Process
Balancing the more pressing needs of a current process with the more strategic needs of a future generation is a daunting task, it can be especially difficult when improving a legacy process. Technical agendas can easily be too narrow, failing to enable necessary design space knowledge or performance enhancements that can be a bridge to the next generation. This is a case study of a plan that attempts to balance the needs of both.

Amanda Ashcraft, Manager, Process Engineering Development, Manufacturing Technical Support, Genzyme

Thursday, October 29 • 4:00 pm pickup time • Destination is Marlborough, MA

NEW! GE Single-Use Biomanufacturing Tour & Technology Workshop
Make the most of your visit to Boston by visiting GE Healthcare Life Sciences Single-Use Biomanufacturing facility in Marlborough, MA. GE will host a private tour and technology workshop demonstrating and discussing flexible and efficient GMP facilities (limited availability). See the factory … Meet the experts … Sign up today!

Contact Jennifer Wickett: (508) 614-1672 • jwickett@ibcusa.com

For up-to-date program information and new abstracts, visit: www.IBCLifeSciences.com/BPI
Regulatory Perspectives on Legacy Products and Post-Approval Manufacturing Changes

4:30 Regulatory Perspectives on Legacy Products
Legacy products are typically those that have been on the market for a decade or more. Legacy products exist because they continue to play an important role in the ongoing treatment of patients. Typically, there are few CMC changes for these products over time unless a safety issue is identified and acted upon either by the sponsor or the regulator. The balance between updating manufacturing and control strategies to better reflect current expectations and the risk to the approval status of the legacy product is currently very conservative. The Canadian regulatory experience with legacy products will be discussed.

Nancy Green, Ph.D., Chief, Hormones and Enzymes Division, CERB, BGTD, Health Canada

5:00 Regulatory Perspective on Post-Approval Manufacturing Changes
Canada has a risk-based program to determine the reporting requirements for post-approval manufacturing changes. Reporting varies between filing an annual notification of a change to filing a supplemental New Drug Submission with supporting non-clinical and/or clinical information. In order to help sponsors determine the appropriate filing level and information requirements, Health Canada has an updated and expanded guidance, the Post-Notice of Compliance Changes Guidance available for consultation. The Canadian experience in using the guidance will be discussed.

Speaker TBA, Health Canada

5:30 Casino Night
Networking Reception in the Exposition Hall
Feeling lucky? Wednesday night’s Networking Reception in the Exposition Hall will feature a Casino Night theme where attendees can try their luck at classic casino games like Blackjack, the Big Six Wheel, and Poker.

Co-Sponsored by BIO-RAD and Life Sciences

Thursday, October 29, 2015

7:00 Bioprocess “Problem-Solving” Discussion Topics and Moderators
These moderated discussions on a variety of bioprocess topics will allow you to share strategies and brainstorm solutions in an informal, small group setting.

QbD for Analytical Methods: Sharing Experiences and Approaches
Kazumi Kobayashi, Ph.D., Senior Principal Scientist, Technical Development, Biogen

Single-use and Disposable Technologies in Bioprocess Development
Wallace Lauzon, Ph.D., Senior Evaluator, Cytokines Division, CERB, BGTD, Health Canada

Regulatory Perspectives on Aging Facilities
Nancy Green, Ph.D., Chief, Hormones and Enzymes Division, CERB, BGTD, Health Canada

Inpection Trends Summary
Jeffrey Skene, Chief, Monoclonal Antibodies Division, CERB, BGTD, Health Canada

Regulatory Perspectives on CMC Submissions
Health Canada Regulator TBA

Particulate Defects - Critical versus Minor
Kevin Kerls, Inspection MSAT, Hillsboro Technical Operations, Genentech, Inc. - A Member of the Roche Group

Opportunities and Challenges of High Concentration Biologics
Mark Moody, Ph.D., Chief Scientific Advisor, ReForm Biologics

Developability and Development: Improving the Outcome
Valentyn Antochnshuk, Ph.D., Principal Scientist, Group Leader, Formulation Design and Process Compatibility, Merck & Co.

Container Closure Integrity Testing and Technology
Kevin M. Maloney, Ph.D., Principal Scientist, Technical Development, Biogen

Raw Materials Management in Biologics Production
Dave Kolwyck, Director, Manufacturing Sciences, Raw Material Global, Process Owner, Biogen

If you are interested in proposing or moderating a discussion topic in this breakfast session, please email at Michael Keenan mkeenan@ibcusa.com.

8:00 Chairperson’s Remarks
Martin Kane, Managing Data Scientist, Exponent Scientific and Engineering Consulting

8:05 Using a Quality by Design Approach to Characterize a CHO-based Monoclonal Antibody Production Process
A Quality by Design (QbD) approach is being employed to characterize a CHO-based cell culture process producing a monoclonal antibody that is in late stage clinical development. The QbD process starts with an analysis of process parameter risk with respect to critical quality attributes (CQAs) and key performance indicators (KPIs). Statistically designed experiments (DOE) and the process parameter ranges tested are based on the outcomes of this risk ranking. These DOE studies screen factors for significant influences (parameter estimates) on CQAs and KPIs. In addition to describing this QbD approach, the results of studies from the seed train, inoculum train and production cell culture steps will be presented.

Jason Goodrick, Senior Engineer and Group Leader, Genentech, A Member of the Roche Group

8:30 Commercial Formulation Selection of a mAb Based on Design of Experiments, Colloidal Solution Properties and Protein Stability at Accelerated Conditions
In this presentation we discuss an approach for the commercial formulation development of a mAb using both empirical and DOE studies. In addition to using conventional biochemical techniques to monitor stability at accelerated conditions, we evaluated colloidal properties and inherent protein stability to assess solvent mediated interactions. Here we describe the utility of solution stability measurements to quickly select a formulation during commercial development.

Moumita Bhattacharya, Ph.D., Senior Scientist, Sterile Product and Analytical Development, Merck

8:55 Characterization and Optimization for Quality-by-Design Using Design of Experiments
Design of Experiments (DOE) are a powerful set of statistical tools that can be used in product and process development to increase knowledge, reduce waste, and innovate at an accelerated pace. This presentation will outline general DOE concepts for factorial and fractional factorial DOE’s and describe several DOE’s that were used in a biopharmaceutical product.

Martin Kane, Managing Data Scientist, Exponent Scientific and Engineering Consulting
Mind the Gaps! Common Mistakes in QC Test Methods vs. Method Validation Packages

Analytical methods used for the quality control (release and stability) testing of pharmaceutical products are expected to be scientifically sound, suitable for their intended uses, and demonstrate they are capable of reliable performance. Biotechnology products can be challenging to analyze because they are large, complex, usually molecularly heterogeneous materials that require numerous orthogonal techniques to assess their physiochemical and functional attributes. Many of the analytical techniques are equally challenging as test procedures in that they involve numerous steps in sample preparation and conduct of the analysis, and often utilize highly variable critical reagents as a part of the method. There are many common mistakes made in QC analytical laboratories that further exacerbate the challenges already present in the test samples and test methods. This talk will highlight some of the most commonly encountered mistakes, and illustrate the most frequent gaps, seen around the world in the implementation of the approaches are paired with example problems (or prevent them before they start!).

Valentyn Antochshuk, Ph.D., Principal Scientist, Group Leader, Formulation Design and Process Compatibility, Merck & Co.

Rapid Microbiological Methods for Real-Time Release of Autologous Cell Therapy Products

Rapid detection of contaminants is essential for autologous cell therapy products with short shelf lives. Developing, validating, and implementing rapid microbiological methods can facilitate real-time release of these products. Application of a risk-based approach during development mitigates most issues prior to validation and facilitates successful implementation.

John Duguid, Principal Scientist, Vericel Corporation

Prediction and Real-Time Control of Product Quality Attributes

This presentation describes and discusses the advantages and disadvantages of four different approaches for the prediction and control of product quality attributes. Descriptions of best-practices implementations of the approaches are paired with example applications to the end-to-end manufacturing of a wide variety of biopharmaceuticals.

Richard D. Braatz, Ph.D., Edwin R. Gilliland Professor of Chemical Engineering, Massachusetts Institute of Technology

Regulatory Perspectives on Phase Appropriate Specification Setting

Ideally, specifications are based upon a thorough analysis of a robust dataset from manufacturing capability and include sufficient safety considerations. In the absence of a validated manufacturing process and sufficient manufacturing history, the setting of specifications for clinical material requires careful consideration of the available data. The specifications must evolve with the development of the product and to the degree possible, ensure the safety of clinical trial participants. The regulatory expectations at different stages of clinical development will be discussed.

Wallace Lauzon, Ph.D., Senior Evaluato, Cytokines Division, CERB, BGTD, Health Canada

CHO Host Cell Proteins and Impacts on Product Formulation

This presentation will discuss an application of genomics and proteomics related to CHO host cell proteins (HCPs). In particular, certain difficult to remove HCPs, identified by proteomics, appear to have an impact on product quality in the context of formulation. We hypothesize that the presence of a specific HCP in polysorbate-containing drug formulations may result in increased degradation rates of polysorbates and discuss our findings related to this hypothesis.

Kelvin H. Lee, Ph.D., Gore Professor of Chemical & Biomolecular Engineering and Director, Delaware Biotechnology Institute, University of Delaware

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Richard D. Braatz, Ph.D., Edwin R. Gilliland Professor of Chemical Engineering, Massachusetts Institute of Technology

Connect the Dots: From Discovery to Manufacturing

How do you ensure that the treatment of a disease can be translated into a successful product? For example, rapid microbiological methods for real-time release of autologous cell therapy products. Developing, validating, and implementing rapid microbiological methods can facilitate real-time release of these products. Application of a risk-based approach during development mitigates most issues prior to validation and facilitates successful implementation.

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Richard D. Braatz, Ph.D., Edwin R. Gilliland Professor of Chemical Engineering, Massachusetts Institute of Technology
Institute for Integrative Cancer Research, Engineering & Biological Engineering; Associate Director, Koch C.P. Dubbs Professor, Chemical will be presented with an eye towards the emergence of such criteria of a large sample of antibodies in commercial clinical development developable antibody drugs? Analysis of a broad spectrum of features structural features consistent with successful drug development. The “Lipinski Rule of 5” provides a widely accepted rule of thumb for expression, stability, solubility, and specificity. For small molecules, binders out of libraries to engineering molecules with industrial-grade expression, stability, solubility, and specificity. For small molecules, the “Lipinski Rule of 5” provides a widely accepted rule of thumb for structural features consistent with successful drug development. The lead can be selected based on expression and product quality of the candidate lead molecules expressed in the intended production system. A case study of such an approach will demonstrate that the long-term success of a new product is enhanced through early investment in parallel development activities.

Susan Dana Jones, Ph.D., Associate Consultant, BioProcess Technology Consultants

Biophysical Properties of Antibody Drugs: What is the Future of Continuous Processing – What is the Time Frame for Implementing Fully Continuous Processing in Commercial Production?

Konstantin Konstantinov, Ph.D., Vice President, Technology Development, Genzyme

Moving Quickly to IND and Beyond

Amgen’s Next-Generation Biomanufacturing Facility

Kimball Hall, Vice President Manufacturing, Amgen Singapore Manufacturing Pte. Ltd.

Biophysical Properties of Antibody Drugs: Predicting and Engineering Developability

The field of antibody engineering has evolved from simply plucking binders out of libraries to engineering molecules with industrial-grade expression, stability, solubility, and specificity. For small molecules, the “Lipinski Rule of 5” provides a widely accepted rule of thumb for structural features consistent with successful drug development. Is there a similar pattern in the values for biophysical properties of a large sample of antibodies in commercial clinical development will be presented with an eye towards the emergence of such criteria for antibodies? Analysis of a broad spectrum of features of a large sample of antibodies in commercial clinical development will be presented with an eye towards the emergence of such criteria for antibodies.

K. Dane Wittrup, Ph.D., C.P. Dubbs Professor, Chemical Engineering & Biological Engineering; Associate Director, Koch Institute for Integrative Cancer Research, Massachusetts Institute of Technology

De-risking Timeline Acceleration and Improving Product Quality: A Case Study of Integrating Lead Selection and Early Development Activities

By initiating early development activities such as cell line development, stress stability testing, and potency assay development prior to lead identification, companies can de-risk their programs while maintaining critical timelines. The lead can be selected based on expression and product quality of the candidate lead molecules expressed in the intended production system. A case study of such an approach will demonstrate that the long-term success of a new product is enhanced through early investment in parallel development activities.

Susan Dana Jones, Ph.D., Vice President and Principal Consultant, BioProcess Technology Consultants

Speeding up Early Stage Biologics Process Development to Move Quickly to Clinical Trials

The rapidly growing demands for therapeutic antibody production and increasing in antibody titer and cell densities have induced the challenges in current harvest and purification technologies. To continuously improve the speed and minimize cost while maintaining quality of the product, new antibody recovery and purification methods are needed. In this presentation, several monoclonal antibody harvest and purification technologies will be reviewed and discussed.

Ji Zheng, Ph.D., Senior Scientist II, Biologics Process Development, Bristol-Myers Squibb

Using Process and Activity to Drive Clone Selection

Oren E. Beske, Ph.D., COO, Aragen Bioscience, Inc

Single-Use Fermentation: Understanding Process Economy and Process Performance

Kenneth Clapp, Senior Global Product Manager, Bioreactors, GE Healthcare

An Insight into Recent Developments in Protein A Chromatography

Jonathan Royce, Senior Product Manager, Bioprocess Product Marketing – Downstream, GE Healthcare

Biological Drug Development from Clone to Clinical to Commercial: Phase-Specific Strategies to Improve Success

The presentation will address factors and approaches to consider for successful transition of biotechnology-derived drug development from the preclinical to Phase 1-3 clinical development, validation, regulatory submission to commercial phase. The focus will be on ensuring manufacturing continuum from process development and controls and analytical development and controls perspectives.

Suketu Desai, Ph.D., Vice President, Biologics Development, Drug Substance and Drug Product R&D, Allergan, Inc.

Phase Appropriate Specifications for Biologics: Trends and Expectations

This discussion will include topics such as establishing initial requirements for the first “Phase I” set of tests and specifications for lot release and how to plan the development of those early specifications to meet later expectations for Phase 2, 3 and commercialization. Coordinating characterization testing, reference standard requirements and stability specifications will also be covered. Current trends in agency requests and expectations for testing and specifications around safety tests will also be presented.

Melissa Morandi, Vice President, Global Quality, Aegerion Pharmaceuticals

Going Small to Understand the Big: Scale-Down Model Qualification and Use in Process Characterization

Scale-down models as an appropriate representation of the manufacturing process are indispensable tools in characterization of biopharmaceutical manufacturing processes. During process development, such models enable evaluation of variability in input materials and parameters on a process and its impact on product quality to an extent that simply is not feasible at manufacturing scale. The key is to keep it simple and appropriate to needs. The presentation shows a pragmatic and systematic approach how to increase understanding of an antibody purification process by enabling elements like scale-down modelling and qualification, cross-functional risk assessments, and process characterization studies.

Klaus Kaiser, Ph.D., Head of Downstream Processing and Analytics, Global Biological Development, Bayer Pharma AG, Germany

For up-to-date program information and new abstracts, visit: www.IBCLifeSciences.com/BPI
3:15 Networking Refreshment Break in the Exposition Hall
Sponsored by PALL Life Sciences

Case Studies

4:00 Effective Management of Internal and External Resources for the Rapid Advancement of Biotherapeutics into Early and Late Clinical Development

Eleven Biotherapeutics is developing recombinant molecules for ophthalmic diseases. One of the molecules is rapidly advancing through late phase clinical trials for Dry Eye Disease. The second is moving towards an IND and Phase 1/2 clinical trial for Diabetic Macular Degeneration. In this presentation we will describe the leveraging of internal and external resources, including internal FTE, academic, CRO and CMO organizations, in a coordinated approach to effectively advance these projects.

Gregory Zarbis-Papastoitis, Ph.D., Vice President of Process and Manufacturing Sciences, Eleven Biotherapeutics

4:30 Late Breaking Early Stage Biologic Presentation
If you have a unique story or a case study about accelerating an early stage biologic quickly to the clinic and beyond and you are interested in presenting in this session, please contact Michael Keenan at mkeenan@ibcus.com

5:00 Rapidly Accelerating Biologics Development Through the Use of CMO’s
Deciding on a strategy for making your first biologic can be a daunting process. For small biotech companies with limited financial and personnel resources, identifying CMO’s who have the right capabilities, cultural fit and can operate in a flexible environment, are important criteria for getting past that first IND Phase 1 milestone, while larger Biopharma have different criteria for choosing a CMO. This talk will present case studies and factors that help accelerate drugs through clinical milestones and discuss how CMOs and be a significant resource.

Susan Dexter, Principal Consultant, Latham Biopharm Group

5:30 Casino Night

Networking Reception in the Exposition Hall
Feeling lucky? Wednesday night’s Networking Reception in the Exposition Hall will feature a Casino Night theme where attendees can try their luck at classic casino games like Blackjack, the Big Six Wheel, and Poker.

Casino Night

NEW! GE Single-Use Biomanufacturing Tour & Technology Workshop
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See the factory … Meet the experts … Sign up today!
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Present a Poster to Showcase Your Novel Research
Share your latest research by presenting a scientific poster during the event. All posters will be displayed in the Exposition Hall for fellow attendees to view and discuss. Poster presenters will be asked to stand by their posters during dedicated poster viewing hours to facilitate networking. All poster submissions are eligible for the Best Poster Award competition sponsored by BioProcess International Magazine. Two winning posters, one academia/industry and one supplier, will be announced live at the BPI Theater and have the opportunity to deliver an oral presentation.

The deadline to submit your poster abstract is September 25, 2015. For more details and to submit your poster abstract, visit www.IBCLifeSciences.com/BPI.

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• Benefit from face-to-face time with new technology companies to learn about tools and streamline your bioprocesses
• Form collaborations and alliances to share the same goals of propelling the bioprocessing industry towards new heights of clinical and commercial success

Information on how to access the application will be emailed to all attendees starting in August 2015. If you registered for the event and do not receive your login information by end of August 2015, contact Howie Choi at hchoi@ibcus.com.

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### Exposition Hall Hours
- **Tuesday, October 27, 2015:** 4:45pm-6:30pm
- **Wednesday, October 28, 2015:** 9:45am-7:00pm
- **Thursday, October 29, 2015:** 9:45am-2:00pm

### Exhibitor List (as of May 27, 2015)
- Advanced Instruments
- AdvantaPure / NewAge Industries
- Applikon Biotechnology
- Aragen Bioscience
- Asahi Kasei Bioprocess
- Avid Bioservices
- BD Biosciences - Advanced Biosciences
- Beckman Coulter Life Science
- Cytovance Biologics
- CPC
- Corning Incorporated
- Cytovance Biologics
- EMD Millipore
- EMD Millipore & Roche
- Entegris
- Eurofins Lancaster Labs
- FeF Chemicals
- FineSens
- Flowmynamics
- FrieslandCampina DOMO
- Fujifilm Diosynth Biotechnologies
- GE Healthcare
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- Infors USA
- Integra Companies
- Irvine Scientific
- JNC Corporation
- KBI Biopharma
- Kemwell Biopharma
- Kuhner Shaker
- Levitronix
- LEWA Nikkiso
- Lonza
- Maryland Biosciences
- MaxCyte
- Meissner Filtration Products
- Nordson Medical
- Nova Biomedical
- Novasep
- Novo Nordisk Pharmatech A/S
- Oetiker, Inc.
- optek-Danulat, Inc.
- Pall Life Sciences
- Paragon Bioservices
- Parker domnick hunter
- Patheon
- PendoTECH
- Pharmatec
- Pneumatic Scale Angelus
- Purolite
- Qosina
- Rentschler Biotechnologie GmbH
- Repilgen
- RheoSense, Inc.
- Roche
- Saint-Gobain
- Sartorius Stedim Biotech
- Sanofi
- Sartorius Stedim Biotech SpectrumLabs.com
- TECAN
- TEK
- Therapure Biomanufacturing
- Thermo Fisher Scientific
- Tosoh Bioscience LLC
- VR Analytical
- Watson-Marlow Fluid Technology Group
- BETC at WPI
- WuXi AppTec
- YSI Life Sciences
- Novasep
- Novo Nordisk Pharmatech A/S
- Oetiker, Inc.
- optek-Danulat, Inc.
- Pall Life Sciences
- Paragon Bioservices
- Parker domnick hunter
- Patheon
- PendoTECH
- Pharmatec
- Pneumatic Scale Angelus
- Purolite
- Qosina
- Rentschler Biotechnologie GmbH
- Repilgen
- RheoSense, Inc.
- Roche
- Saint-Gobain
- Sartorius Stedim Biotech
- Sanofi
- Sartorius Stedim Biotech SpectrumLabs.com
- TECAN
- TEK
- Therapure Biomanufacturing
- Thermo Fisher Scientific
- Tosoh Bioscience LLC
- VR Analytical
- Watson-Marlow Fluid Technology Group
- BETC at WPI
- WuXi AppTec
- YSI Life Sciences

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- Industry moderators and commentators
- **NEW! “Ask the Regulators” Open Forum:** A CMC Regulatory Discussion
- **Fireside Chat:** An Interactive Panel Discussion on How to Accelerate Biopharmaceutical Development and Manufacturing.
- **New Product Showcases**
- **Featured Presentation:** Academic Institutions Response to the Workforce Training Demands of the Biomanufacturing Industry, presented by Worcester Polytechnic Institute
- Technology demonstrations
- Live speaker interviews and Q&A
- “Themed” and expanded oral poster sessions
- BPI Best Poster Award Winner Presentations
- New product launch presentations
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We understand that your company needs to extend reach beyond the Exposition Hall in order to build relationships and connect with attendees. Whether you are an established player in the market or are looking to break into the industry, IBC offers a variety of creative packages to offer you high-level exposure to senior decision makers, including:

**Product Launch in the BioProcess International Theater**
Showcase your company’s expertise in the BPI Theater. Take advantage of this opportunity to deliver a 20-minute Product Launch presentation directly to the decision makers and end-users with real purchasing power.

**Thought Leadership Programs**
BPI provides sponsorship opportunities that help you demonstrate your thought leadership to our highly targeted audience. A variety of thought-leadership solutions are available, including technology workshop speaking slots, pre and post-event web seminars and panel participation.

**Digital Marketing Programs**
Generating buzz going into a major event is good for your business. Let IBC Life Sciences help you stimulate demand for your products and services with a custom podcast featured in the BioProcess International 2015 Podcast Series. IBC can also help you develop a customized digital marketing program that combines podcasts with banners, e-newsletters, white papers, webinars and more.

**Branding Opportunities**
Take advantage of BPI’s impactful branding program to strengthen your company brand. Branding opportunities are available during networking breaks, breakfasts, and luncheons or on high visibility items such as tote bags, padfolios, or lanyards.

To find out what the best level of sponsorship is for your organization, please contact:
Jennifer Wickett, A-L: (508) 614-1672 • jwickett@ibcusa.com OR Kristen Schott, M-Z: (508) 614-1239 • kschott@ibcusa.com

For up-to-date program information and new abstracts, visit: www.IBCLifeSciences.com/BPI

**EXPOSURE AND ACCESS TO KEY DECISION MAKERS**

**BY GEOGRAPHY**

- North America 76%
- Asia 11%
- Europe 13%

**Senior Scientists and Key Decision Makers Are Looking to Connect With These Types of Industry Experts:**
- CMO/CRO
- Laboratory Instrumentation and Automation Suppliers
- Cell Culture, Media, Raw Material Suppliers
- Chromatography and Purification Equipment Suppliers
- BioProcessing Technology Providers
- Formulation Design and Technology Providers
- Process Components, Supplies & Instrumentation
- Inspection, Testing and Packaging Technology Providers
- Analytical Instrumentation and Equipment Suppliers
- Single-Use Technology and Component Suppliers
- Facility Design & Construction Services
- Drug Product and Fill-Finish Processing Services
### Industry Rates

<table>
<thead>
<tr>
<th>Service Description</th>
<th>Save up to $500 by June 12, 2015</th>
<th>Save up to $400 by July 17, 2015</th>
<th>Save up to $300 by August 21, 2015</th>
<th>Save up to $200 by September 25, 2015</th>
<th>Standard Rate After September 25, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BEST VALUE</strong> - <strong>4-Day Access</strong>: 2-Day Training Course (Mon-Tues) + 2-Day Main Conference (Wed-Thurs)</td>
<td>$2,499</td>
<td>$2,699</td>
<td>$2,799</td>
<td>$2,899</td>
<td>$3,099</td>
</tr>
<tr>
<td><strong>4-Day Access</strong>: Pre-Conference Symposia (Mon) + 3-Day Main Conference (Tues-Thurs)</td>
<td>$2,599</td>
<td>$2,599</td>
<td>$2,699</td>
<td>$2,799</td>
<td>$2,999</td>
</tr>
<tr>
<td><strong>3-Day Access</strong>: Main Conference (Tues-Thurs)</td>
<td>$1,899</td>
<td>$1,999</td>
<td>$2,099</td>
<td>$2,199</td>
<td>$2,399</td>
</tr>
<tr>
<td><strong>2-Day Training Course Only</strong> (Mon-Tues)</td>
<td>$1,499</td>
<td>$1,599</td>
<td>$1,699</td>
<td>$1,799</td>
<td>$1,999</td>
</tr>
</tbody>
</table>

### Group Rates (Send 4 or more)

<table>
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<tr>
<th>Service Description</th>
<th>Save up to $500 by June 12, 2015</th>
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</tr>
</thead>
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<tr>
<td><strong>BEST VALUE</strong> - <strong>4-Day Access</strong>: 2-Day Training Course (Mon-Tues) + 2-Day Main Conference (Wed-Thurs)</td>
<td>$2,099 per person</td>
<td>$2,299 per person</td>
<td>$2,399 per person</td>
<td>$2,499 per person</td>
<td>$2,699 per person</td>
</tr>
<tr>
<td><strong>4-Day Access</strong>: Pre-Conference Symposia (Mon) + 3-Day Main Conference (Tues-Thurs)</td>
<td>$2,199 per person</td>
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<td>$2,299 per person</td>
<td>$2,399 per person</td>
<td>$2,599 per person</td>
</tr>
<tr>
<td><strong>3-Day Access</strong>: Main Conference (Tues-Thurs)</td>
<td>$1,699 per person</td>
<td>$1,799 per person</td>
<td>$1,899 per person</td>
<td>$1,999 per person</td>
<td>$2,199 per person</td>
</tr>
</tbody>
</table>

### Academic/Government Rates are Available
Full-time employees of a government organization, universities and university-affiliated hospitals are eligible to take advantage of up to 40% savings off industry rates. Visit our website for more details and academic/government pricing.

### Present a Poster to Enhance Your Conference Experience
All poster presenters must be registered conference attendees. The fee to present a poster in addition to your conference registration is: Poster Fee: $125 Academic/Government: Free

### Conference Venue
**John B Hynes Veterans Memorial Convention Center**
900 Boylston Street, Boston, MA 02116, United States
Ph: (617) 954-2000 • massconvention.com

### Hotel Accommodations
**Hilton Boston Back Bay** $279 (plus taxes)
40 Dalton Street, Boston, MA 02115
Ph: (617) 236-1100 • Hilton Reservations, call (800) 445-8667
Please call the hotel directly before Friday, October 9, 2015 or until room block is sold-out

**Sheraton Boston** $299 (plus taxes)
39 Dalton Street, Boston, MA 02119
Ph: (617) 236-2000 • Sheraton Reservations, call (888) 627-7054
Please call the hotel directly before Friday, October 2, 2015 or until room block is sold-out
Please identify yourself as a participant in IBC’s BPI (BioProcess International) Conference to receive the reduced room rate. Reservations are subject to availability. The hotel will require a first and last night’s non-refundable deposit at the time the reservation is made.

For details regarding IBC’s cancellation and substitution policy, visit [www.IBCLifeSciences.com/BPI](http://www.IBCLifeSciences.com/BPI)

### Train Your Team at BPI and Save
Register your team of 4+ to save up to an additional $400/person off the current industry rate. Secure your team’s place today by calling group sales manager Millison Thenor at mthenor@ibcusa.com or 646-895-7423.

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NEW THIS YEAR!

Propel your API Towards a Finished Commercial Product
by attending the new Drug Product Manufacturing & Fill-Finish Processing track

Ensure your Drug Candidate Meets Regulatory Expectations
by participating in the new regulatory panel discussion to gain the guidance you need for CMC success

Grow your Business
by finding new customers and potential partners easier than ever with the new and improved BPI Connect networking app

Evaluate New Technologies and Understand Industry Trends
in the expanded BPI Theater featuring new product launches, hot-topic panel discussions, speaker interviews and more

Overcome Your Current Challenges
by attending the new problem-solving breakfast roundtable discussion where you can brainstorm solutions to your toughest challenges in a small and intimate networking environment

“This is a one-stop, non-stop conference. You can personalize your day by selecting presentations from different tracks with an option to gain more knowledge by visiting the Exposition Hall, reading posters, attending a training course, and taking a tour of a local manufacturing plant.”
- Rebecca Bartkus, Millipore

Industry Experts Showcase Novel Insights that Foster Real Change

Innovating mAb Production
David J. Pollard, Ph.D.
Merck & Co. Inc.

Next-Generation Biomanufacturing Facility
Kimball Hall
Amgen

Innovative Process Development Strategies
Spencer Fisk
Novartis, Switzerland

Developing and Producing Experimental Vaccines for HIV
Michael Anthony (Tony) Moody, M.D.,
Duke School of Medicine

The Future of Continuous Processing
Konstantin Konstantinov, Ph.D.
Genzyme

Learn more and register today at www.IBCLifeSciences.com/BPI