

The most influential bioprocessing event in 2005!
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BioProcessTM INTERNATIONAL

WORLD CONFERENCE & EXHIBITION

Conference: September 19-22, 2005 • Exhibition: September 19-21, 2005
The Boston Convention & Exhibition Center, Boston, MA

Keynote Presenters:

Ronald C. Branning,
Genentech, Inc.

H. Michael Koplove, Ph.D.,
Wyeth BioPharma Operations Network

Duncan Low, Ph.D., Amgen, Inc.

Karl Dane Wittrup, Ph.D., MIT

Michael W. Glacken, Ph.D.,
Millennium Pharmaceuticals, Inc.

Featured Presenter:

Anthony R. Mire-Sluis, Ph.D., Amgen, Inc.

Plus:

Behind-the-scene accounts of **AvastinTM**,
Erbix[®] and **HUMIRATM**

Site tours to **Applied Biosystems** and
Genzyme Corporation

*Customize Your Conference Experience
with 4 Flex-Track Modules*

1	Production & Economics	
2	Scaling Up from Bench to Clinic	
3	Cell Culture & Upstream Processing	
4	Recovery & Purification	

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Companies across the biopharm industry embraced the inaugural event in October 2004, commending IBC Life Sciences and BioProcess International[™] for creating an experience much needed by the industry! The 2005 event continues this experience, featuring the popular four-module format, allowing you the flexibility to attend presentations across the modules of most interest to you.

1 Production & Economics

Monday, September 19 - Wednesday, September 21, 2005

- Strategic planning for efficient manufacturing from **Genentech, Boehringer Ingelheim**
- Benchmarking data on capacity and production trends
- Analysis of current drivers in process economics with **Millennium** on competitive pricing pressures and life cycle management, **Seattle Genetics** on highly potent drugs, and **Antigenics** on patient-specific immunotherapy
- **Merck's** experience with modular manufacturing plus a small group break-out session on facilities with leading industry players
- Discussion groups on alternative expression systems, quality by design and single-use processes

2 Scaling Up from Bench to Clinic

Monday, September 19 - Wednesday, September 21, 2005

- **Scale-down strategies from Protherics, Amgen** and Gail Sofer of **GE Healthcare**
- European regulatory perspective on comparability from the **AFSSAPS (French Regulatory Agency)**
- Case studies in using comparability to demonstrate equivalence from **Amgen, Meristem Therapeutics** and **Protein Design Labs**
- Scale up case studies from **Raven biotechnologies, inc., Genentech** and **DOR BioPharma**
- **Abbott's** high throughput screening approach during cell line development to improve productivity and expectations
- Optional Workshop on CMOs: **Select, Contract and Maintain Relationships** (see BPI Seminar Series Insert for details)

3 Cell Culture & Upstream Processing

Tuesday, September 20 - Thursday, September 22, 2005

- **Wyeth's** approaches to shorter process development timelines and increased productivity using high throughput screening
- Lessons learned from the application of scale-down and robustness studies to process validation, process transfer, and post-approval changes
- Case study on **Amgen's** comparison of disposable and stainless steel bioreactors for growth, protein expression and product quality
- Tactics for early identification and assessment of product quality attributes and their integration into process development from **Genentech** and **MedImmune**
- New reports detailing impact of cell culture quality on downstream processing operations from **Amgen, Wyeth BioPharma** and **Bayer Healthcare**

4 Recovery & Purification

Tuesday, September 20 - Thursday, September 22, 2005

- Case studies on domestic and international technology transfers from **Abbott, Altus, Avecia, Lonza, Protein Design Labs** and **Diosynth Biotechnology**
- Recovery Strategies to optimize yield, productivity and quality from **Amgen, Merck, Abbott** and **BaroFold**
- Application of high throughput screening to a monoclonal antibody purification platform from **Wyeth BioPharma**
- A manufacturing perspective of the separation of early and late stage development from **Genentech**
- Impact of international regulations, viral clearance requirements and evolving cGMPs on purification process development and validation

Design the program to your specific interests:

3-Day Pass Attend three focused days of the module that matches your needs and participate in any relevant sessions from the other modules taking place on the same days. You decide which three days you come for: Monday through Wednesday (Modules 1 & 2) or Tuesday through Thursday (Modules 3 and 4). This mix-and-match programming allows you to organize your schedule around your module of choice, creating a highly-customized conference schedule.

4-Day Pass Benefit from a multi-conference experience in a single trip for one low registration fee. Attend sessions that best match your needs from every module. If you are attending Module 1 or 2, gain more "nuts and bolts" technical information by staying for Thursday's programming. If you are attending Module 3 or 4, consider arriving Monday to attend the strategic level presentations on process development and economics.

All conference attendees with a 3- or 4-day pass receive a CD-ROM with presentations from all four modules.

Keynote Presentations

Monday, September 19, 2005 • 4:30 p.m.



Quality Partnerships – The Lowest Cost and Most Efficient “Carpool Lane” to Product Approval

The carpool analogy to product approval is appropriate for two reasons: 1) you're all on the journey together and 2) depending on the arrangements, each of you takes your turn in the driver's seat. This keynote will address the need for a framework approach to the R&D, process development and commercial production transitions to control cost and quality.

Ronald C. Branning, Vice President, Commercial Quality, Genentech, Inc.

Monday, September 19, 2005 • 5:15 p.m.



Building, Buying, Remodeling and Selling Biopharmaceutical Facilities: A Tale of Two Facilities

The biopharmaceutical industry is a high-roller's game. A great drug concept often requires a great capital investment without a great deal of information. When products do not fulfill their forecasts, investment opportunities arise. Over the last decade or two, we've had the opportunity to sell the same facility twice, and buy and sell another facility that had been sold three times before. See if you can top that!

H. Michael Koplove, Ph.D., Vice President, Wyeth BioPharma Operations Network

Tuesday, September 20, 2005 • 8:00 a.m.



Identification of Important Process Engineering Problems Requiring Joint Efforts of Biologists and Engineers

This address will review the history and benefits derived from the collaboration of biologists and engineers towards biopharmaceutical process issues. Examples include: (i) creation/selection of process-optimized cell lines; (ii) the interplay between protein quality and process environment; (iii) metabolic engineering; and (iv) application of high throughput discovery technology to process development.

Michael W. Glacken, Ph.D., Associate Director, Process Development, Head, Biologics Process Development, Millennium Pharmaceuticals, Inc.

Tuesday, September 20, 2005 • 5:00 p.m.



Current Practices and Future Directions in Bioprocessing

This presentation analyzes current industry best practices and looks at how new technologies will impact the industry to give higher titres, better yields and shorten time to market. High throughput development tools are available for further improvements in cell culture development, and higher capacity purification tools will be needed to cope with the ever increasing quantities emerging from bioreactors. The ability to implement improvements will change as better tools are available to characterize and understand processes and through the use of Process Analytical Technologies.

Duncan Low, Ph.D., Scientific Director, Process Development, Amgen, Inc.

Wednesday, September 21, 2005 • 8:00 a.m.



Protein Engineering in Biomedicine

We have developed a yeast surface display directed evolution method for essentially arbitrary manipulation of protein binding free energy, protein expression, and thermal stability. Applications of protein engineering to the following problems will be discussed: tumor targeting; interleukin-2 pharmacokinetics; and Huntington's disease.

Karl Dane Wittrup, Ph.D., J.R. Mares Professor, Chemical Engineering & Biological Engineering, Massachusetts Institute of Technology

Site Tours

Wednesday, September 21, 2005 • 2:00 p.m.

Tour one of the following facilities! **You must register for a 3-day or 4-day pass and specify which tour you wish to attend by August 22.** Space is available on a first-come, first-served basis and is very limited.

Be sure to identify the site tour you wish to attend in Step 3 on the registration form, or inform customer service if you register by phone. We will notify you by August 29 if you will be attending the tour. Buses depart the convention center at 2:00 p.m. and you will arrive back at the hotels between 5:30-6:00.

Back by Popular Demand!

AB Applied Biosystems

OPEN TO 75 PEOPLE

Visit Applied Biosystems' new 30,000 ft² process chromatography manufacturing facility, designed for the production of POROS® Perfusion Chromatography® media, located on its campus in Bedford, MA. POROS® Perfusion Chromatography® media is the highest performance chromatography media for process separations and is used for the production of multiple FDA approved biotherapeutics. The newly opened Bedford production facility represents a 4x production capacity increase over its previous manufacturing plant and produces products backed up by a registered, ISO 9001:2000 quality system. Gain unique insight into the manufacturing processes, quality, systems and facilities used to produce high performance Protein A and Ion exchange media for the bioprocess industry. The tour will include an overview of POROS® Perfusion Chromatography® products as well as the design, validation and operation of this new facility.

genzyme
GENERAL
pharmaceuticals

Allston Landing Facility

OPEN TO 40 PEOPLE

Tour the Allston Landing Facility, a licensed manufacturing site of Genzyme Corporation, one of the world's leading biotechnology companies. The 180,000 square foot facility has bulk manufacturing capacity for multiple products utilizing recombinant mammalian cell culture. Six 2,000 L bioreactors are used to produce recombinant enzyme products. The facility also has product filling and lyophilization capability. Commercial products currently manufactured or packaged at the Allston Landing Facility include: Cerezyme®, Fabrazyme®, Thyrogen® and Aldurazyme®.



Agenda-at-a-Glance

1 Production & Economics


2 Scaling Up from Bench to Clinic

3 Cell Culture & Upstream Processing

4 Recovery & Purification

Monday, September 19, 2005

Exhibit Hall Opens: 6:00-7:15 pm

7:30 am	Registration		
8:30-12:15 pm	Strategic Planning for Efficient Manufacturing	Regulatory Trends and Use of Comparability for Demonstrating Equivalence	 <p>With the 4-Day Pass, attendees of Modules 3 and 4 can also attend Monday's strategic-level sessions and the Monday evening keynote from Modules 1 and 2.</p>
1:30-4:15 pm	Current Drivers in Process Economics	Scale-Down Technologies and Case Studies in Scaling Up	
4:30-5:15 pm	Keynote: Quality Partnerships – The Lowest Cost and Most Efficient “Carpool Lane” to Product Approval – Ronald C. Branning, Genentech, Inc.		
5:15-6:00 pm	Keynote: Building, Buying, Remodeling and Selling Biopharmaceutical Facilities: A Tale of Two Facilities H. Michael Koplove, Ph.D., Vice President, Wyeth BioPharma Operations Network		
6:00-7:15 pm	Exhibit Hall Opens with Cocktail Reception sponsored by SAFC Pharma		

Tuesday, September 20, 2005

Exhibition Hours: 10:15 am-7:00 pm

7:30 am	Registration		
8:00-8:45 am	Keynote: Identification of Important Process Engineering Problems Requiring Joint Efforts of Biologists and Engineers Michael W. Glacken, Ph.D., Millennium Pharmaceuticals, Inc.		
8:45am-12:00pm	Optimizing Asset Utilization through Modeling and New Technologies	Cell Line Development and Clone Selection	Optimizing Asset Utilization through Modeling and New Technologies
12:00-12:30 pm	Technology Workshops: Millipore or Stedim or SAFC Pharma		
12:30-2:00 pm	Lunch in Exhibit Hall		
2:00-3:40 pm	Manufacturing Success Stories: HUMIRA™, Avastin™ and Erbitux®		
4:20-5:00 pm	Featured Presentation: Scaling Up and Transferring your Process: To Improve or Not Improve? That is the (Regulatory) Question Anthony R. Mire-Sluis, Ph.D., Amgen, Inc.		
5:00-5:45 pm	Keynote Presentation: Current Practices and Future Directions in Bioprocessing – Duncan Low, Ph.D., Amgen, Inc.		
5:45-7:00 pm	Networking Cocktail Reception, Poster and Exhibit Viewing Sponsored by BioProcess™ International		
6:00-7:00 pm	Dedicated Poster Viewing		


Wednesday, September 21, 2005

Exhibition Hours: 9:45 am – 2:00 pm

7:30-8:00 am	Technology Workshop - Althea Technologies, Inc.		
8:00-8:40 am	Keynote Presentation: Protein Engineering in Biomedicine – Karl Dane Wittrup, Ph.D., Massachusetts Institute of Technology		
9:00 am-12:00 pm	Concurrent Break-Out Sessions	8:10-12:00 Process and Manufacturing Scale Up	Recovery Approaches
12:00-12:30 pm	Technology Workshops: GE Healthcare OR Sartorius OR SAFC Pharma		
2:00-5:30 pm	<i>Choose from the following:</i> Technology Transfer OR Applied Biosystems Site Tour OR Genzyme Corporation Site Tour	The Good, the Bad and the Ugly... Technology Transfer of Downstream Processes	Media Development and Optimization The Good, the Bad and the Ugly... Technology Transfer of Downstream Processes

Thursday, September 22, 2005

Exhibition Hall is Closed

8:30 am-12:15 pm	With the 4-Day Pass , attendees of Modules 1 and 2 can also attend the In-Depth Technology Tracks on Thursday from Modules 3 and 4. 	Process Characterization and Validation & Post Approval Process Improvements	Streamlining of Rapid Process Development & Worldwide Regulatory Implications for Recovery and Purification
12:15-2:00 pm		Technology Workshop and Luncheon Sponsored by Pall Life Sciences	
1:30-4:30 pm		2:00-4:30 How Upstream Affects Downstream Processing	Transitions from Early to Late Phase to Commercial & Emerging Applications for New Sensors and Process Control



Scientific Advisory Board

- Wolfram Carius, Ph.D.**, *Senior Vice President, Biopharmaceuticals, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany*
- Parrish M. Galliher**, *President and CTO, Xcellerex Inc.*
- Peter Latham**, *President, BioPharm Services US*
- Howard L. Levine, Ph.D.**, *President, BioProcess Technology Consultants*
- Rick J. Rutter, Ph.D.**, *Vice President, Pharmaceutical Sciences, St. Louis Global Biologics, Pfizer Inc.*
- Scott M. Wheelwright, Ph.D.**, *President and CEO, Strategic Manufacturing Worldwide*

Monday, September 19, 2005

7:30 *Registration and Coffee*

Strategic Planning for Efficient Manufacturing

8:30 **Chairperson's Remarks**
 Scott M. Wheelwright, Ph.D., *President, Strategic Manufacturing Worldwide*

8:45 **The State of Biomanufacturing Capacity – Do We Finally Have Enough?**
 We have updated our previous estimates of the supply and demand for biomanufacturing capacity. Our analysis indicates demand for cell culture manufacturing capacity will continue to increase with supply roughly matching this demand as several companies bring new and/or renovated facilities online. Access to and availability of capacity for companies seeking to outsource production may result in short-term constraints.

Howard L. Levine, Ph.D., *President, BioProcess Technology Consultants*

9:15 **Survey Results – International Capacity and Production Trends in Biopharmaceutical Manufacturing**

Session summarizes results of 3rd Annual Report on Biopharmaceutical Manufacturing Capacity and Production (ASM Press study). Includes benchmarking data from 187 biomanufacturers, worldwide: Capacity constraints, 2005-2010; capacity utilization; avoiding capacity constraints; capacity expansions, 2010; outsourcing, by production system, 2005-2010; CMO selection issues; disposables and single-use systems—reasons for increasing / restricting use; downstream purification and microfiltration trends; training in biomanufacturing, in-house vs. external providers.

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

9:45 **Modular Biopharmaceutical Manufacturing Plants – An Owner's Perspective**

The need to quickly position capital assets to support biopharmaceutical industry competitive conditions requires use of construction strategies beyond “stick-built” facilities. The utilization of modular construction is one such approach. Maximizing modular construction performance is enhanced by implementing a design-build approach. Factors to consider in cost and risk forecasting are given in this presentation from the owner's perspective.

Carrier F. Li, *Project Design Manager, Merck & Co, Inc.*

10:15 *Networking Refreshment Break*

10:45 **Quality by Design: Integration of Research, Clinical and Process Development from Start to Finish**

CASE STUDY

The development of a robust and commercially viable biotechnology process requires careful planning throughout all stages of clinical development. Decisions that are made early-on in terms of molecule selection, process and method development, and clinical manufacturing can have significant impact on the commercial process capability and ultimately product specifications. Examples highlighting the importance of the above concepts are presented.

Wassim Nashabeh, Ph.D., *Quality Control Clinical Director, Genentech, Inc.*

11:15 **Management Execution Systems in Biotech – Profit or Pain?**

In 2004 Boehringer Ingelheim started up a large-scale mammalian cell culture facility in which – for the first time in Biotech production – a Manufacturing Execution System (MES) closes the automation gap between the Enterprise Resource Planning (ERP) and the field automation. Targeted for compliance as well as continuous process improvement, this MES controls and documents automatically the manufacturing process through complete electronic batch processing and recording.

Guenter M. Oswald, *Head of Engineering and Technology, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany*

11:45 **Bioprocessing in Asia: Now and the Next 5 Years**

Biotechnology activities have expanded rapidly in Asia. In addition to outsourcing of active pharmaceutical ingredients and research, we now see the establishment of subsidiary operations for product development that take advantage of favorable labor rates and government incentives. Changes in the legal framework, including patent protection for drugs in India and outsourcing in Japan, provide additional opportunities in bioprocessing.

Scott M. Wheelwright, Ph.D., *President, Strategic Manufacturing Worldwide*

12:15 *Free Time*

Current Drivers in Process Economics

1:30 **Chairperson's Remarks**
Parrish M. Galliher, *President and CTO, Xcellerex Inc.*

1:45 **Biotechnology Grows-Up: The Effect of Competitive Pressure and Life Cycle Management (LCM) on Process Development**

CASE STUDY

Pressures on pricing and reimbursement, process advancement in protein production, and extremely competitive markets in inflammation and oncology indications have combined with traditional issues to make development challenging. To be successful, process development must be an integral part of LCM that interacts with the clinical, regulatory and marketing plans.

Bob J. Steinger, *Vice President, Process Sciences, Millennium Pharmaceuticals, Inc.*

2:15 **Biopharmaceuticals and Biodefense: Public-Private Partnership Opportunities in the Fight Against Pandemics and Bioterrorism**

The threat of bioterrorism and emerging and reemerging pathogens have dominated government infectious disease R&D and public health policy since the attacks of 2001. This presentation describes some of the recent government initiatives designed to engage pharmaceutical and biotechnology companies in partnerships for drug and vaccine development, as well as the political and policy trends that drive these programs and favor some firms over others.

Michael J. Eichberg, Ph.D., *Principal, Health Security Strategies and BioRosettex-Sarnoff Corporation*

2:45 *Networking Refreshment Break*

3:15 **Process Development and Manufacture of Highly Potent Antibody-Drug Conjugates for Cancer Therapy**

Several technologies are being developed to enhance the potency and effectiveness of monoclonal antibody therapies. One such approach is the conjugation of highly potent cytotoxin drugs to antibodies specific for antigens over-expressed in certain cancers. We have developed a technology platform based on the conjugation of auristatins through a stable, enzyme-cleavable peptide linker. The implications of the resulting increased potency on the process development and commercial manufacturing of antibody drug conjugates are discussed.

Morris Rosenberg, Ph.D., *Senior Vice President, Development, Seattle Genetics*

Monday, September 19, 2005 *(continued)***3:45 Manufacturing and Control of an Autologous Biopharmaceutical**

Oncophage is a novel, patient-specific immunotherapy for the treatment of cancer comprised of a protein-peptide complex purified from a resected tumor and administered back to the individual patient to stimulate a tumor specific immune response. The successful manufacture, control and logistics as well as the establishment of systems to satisfy the unique regulatory requirements for this unprecedented product are discussed.

Mario DiPaola, Ph.D., Senior Director of Manufacturing Operations, Antigenics, Inc.

4:15 Brief Break for Room Change**4:30 Keynote Presentation****Quality Partnerships – The Lowest Cost and Most Efficient “Carpool Lane” to Product Approval**

Please see abstract on p. 3.

Ronald C. Branning, Vice President, Commercial Quality, Genentech, Inc.

5:15 Keynote Presentation**Building, Buying, Remodeling and Selling Biopharmaceutical Facilities: A Tale of Two Facilities**

Please see abstract on p. 3.

H. Michael Koplove, Ph.D., Vice President Biopharma Operations Network, Wyeth Biopharma

6:00 Exhibit Hall Opens with Networking Cocktail Reception

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Inspiring Science[™]

Learn about new technologies and services from over 80 exhibiting companies. Make new contacts while enjoying beverages and hors d'oeuvres. Learn new data from a large group of poster presentations.

Tuesday, September 20, 2005**7:00 Coffee****8:00 Keynote Presentation****Identification of Important Process Engineering Problems Requiring Joint Efforts of Biologists and Engineers**

Please see abstract on p. 3.

Michael W. Glacken, Ph.D., Senior Scientist II, Process Development, Millennium Pharmaceuticals, Inc.

Optimizing Asset Utilization through Modeling and New Technologies**8:45 Chairperson's Remarks**

Peter Latham, President, BioPharm Services US

9:00 Scheduling Models for De-bottlenecking and Throughput Analysis for Large-Scale Cell Culture Production**CASE STUDY**

Scheduling models developed for two large-scale cell culture manufacturing facilities are presented. The models were used to perform optimization and de-bottlenecking analysis at one facility, and process-fit and throughput analysis at another. The models have proven to be very useful tools for conceptual engineering, retrofitting and optimization.

Alex Fotopoulos, Associate Director, Engineering, Biogen Idec

9:30 Optimization of Manufacturing Operations Using Discrete Event Simulation

The presentation describes Avecia's experiences optimizing multi-product manufacturing operations through use of modeling. The presentation assesses alternative capital and non-capital options, risk reduction when introducing new products and provides insight into human resource and plant constraints for different processes. Plans to improve operational effectiveness by integrating model use within the organization are also explained.

Bruce Williams, Manufacturing Technology Manager, Avecia Biotechnology, United Kingdom

10:00 Networking Refreshment Break with Exhibit and Poster Viewing**10:30 Capacity Utilization Modeling for Process Development Scheduling****CASE STUDY**

Development groups frequently face multiple products, limited resources and tight timelines. To address these challenges, we have adapted a capacity utilization modeling platform to schedule and de-bottleneck drug development from cell line development to GMP production. This presentation describes the results of our modeling efforts.

Nicolina Hull-Campbell, Pharmaceutical Development Scientist, Xoma (US) LLC

11:00 The Use of Spreadsheet Process Modeling in Facility Design

Unither Pharmaceuticals was faced with the challenge of outsourcing or building manufacturing capacity. We used a spreadsheet model of our manufacturing process to evaluate this make-buy decision and to select an optimum process scale for our facility. This presentation analyzes how spreadsheet process modeling can be used to make informed decisions about manufacturing capacity and in facility design.

Jim Levin, D.V.M., Vice President, Manufacturing and Development, United Therapeutics Corp.

11:30 An Analysis of Single-Use Disposables Technology from an Experienced User's Perspective

Dr. Wong reports on technology development, requirements for implementation, facets of disposable assembly design and troubleshooting. Factors to consider in the decision to go to disposables are analyzed.

Russell Wong, Ph.D., Senior Process Development Engineer, Biological Products, Bayer Healthcare

12:00 Technology Workshops

Hear about the latest technologies directly from the developers. Please see page 20 for workshop options and details.

12:30 Luncheon and Poster/Exhibit Viewing**Manufacturing Success Stories****2:00 Chairperson's Remarks**

Howard L. Levine, Ph.D., President, BioProcess Technology Consultants

2:10 HUMIRA[™]: Just In Time Manufacturing?**CASE STUDY**

HUMIRA[™] (Adalimumab) is a fully human monoclonal antibody used for the treatment of rheumatoid arthritis. From the start of clinical development in 1997 and since market launch in 2003, a combination of facility expansions and process improvements was utilized to meet the increasing demand for this product, while trying to minimize the financial commitment at risk during the development cycle. This presentation illustrates the path taken and some of the resulting challenges and lessons learned.

Peter F. Moesta, Ph.D., Divisional Vice President, Biologics Manufacturing, Global Pharmaceutical Operations, Abbott Bioresearch Center

2:40 **Critical Process Parameters (CPP's) and System Design for Product Approval – Avastin™ Highlights** **CASE STUDY**

The rapid approval of Avastin by FDA was facilitated by Genentech's approach to the identification and confirmation of critical process parameters and the assessment and delineation of process monitoring and control points to assure product quality. This presentation will include the framework for process development, risk assessment and the use of PAT for process monitoring and control.

Ronald C. Branning, *Vice President, Commercial Quality, Genentech, Inc.*

3:10 **The Second Erbitux® Plant: What Does a \$260 Million Investment Really Mean?** **CASE STUDY**

Erbitux® is a chimeric monoclonal antibody approved in the US and many European countries for treating refractory colorectal cancer patients. This presentation reviews the status of the design, construction and costs of a second, multi-product production plant that will be used to produce Erbitux® and other products.

S. Joseph Tarnowski, Ph.D., *Senior Vice President, Manufacturing Operations and Product Development, ImClone Systems Inc.*

3:40 *Poster/Exhibit Viewing and Networking Refreshment Break*

Featured Presentation

4:20 **Scaling Up and Transferring your Process: To Improve or Not Improve? That is the (Regulatory) Question**

It is an expectation that scale up will occur during the commercialization of biotechnology products, and this often involves the transfer of the process either within or between sites. There are regulatory requirements and expectations to assess comparability of both product and process. Making changes to the process at this stage requires a well designed strategy involving risk assessment, process characterization and monitoring and statistical data evaluation.

Anthony R. Mire-Sluis, Ph.D., *Head of Product Quality and External Affairs, Amgen, Inc.*

5:00 **Keynote Presentation**
Current Practices and Future Directions in Bioprocessing

Please see abstract on p. 3.

Duncan Low, Ph.D., *Scientific Director, Process Development, Amgen, Inc.*

5:45 *Networking Cocktail Reception in Exhibit Hall*

6:00–7:00 *Dedicated Poster Viewing*

Wednesday, September 21, 2005

7:15 *Coffee and Breakfast Pastries*

7:30 **Technology Workshop**

Hear about the latest technologies directly from the developers.

Please see page 20 for workshop options and details.

8:00 **Keynote Presentation**
Protein Engineering in Biomedicine

Please see abstract on p. 3.

Karl Dane Wittrup, Ph.D., *J.R. Mares Professor, Chemical Engineering & Biological Engineering, Massachusetts Institute of Technology*

Consider sending new colleagues in your group to the "Introduction to Biopharm Manufacturing" seminar, taught by Scott Wheelwright, Ph.D.

See seminar insert or visit www.IBCLifeSciences.com/3124

8:40 *Brief Break for Room Change*

Concurrent Break-Out Discussions

9:00 **Critical Industry Challenges**

Discuss today's bottlenecks, obstacles and risks with your colleagues in informal, small group settings. Learn the behind-the-scenes activities that you rarely discuss in large conference meeting rooms, but you can air in these focused discussions.

Protein Expression Systems: Alternative Ways to Make and Deliver Proteins

Co-moderators:

Tom Ransohoff, *Senior Consultant, BioProcess Technology Consultants*

Bob J. Steininger, *Vice President, Process Sciences, Millennium Pharmaceuticals, Inc.*

Facilities: Comparing Benefits and Challenges of Stick Built vs. Modular

Co-moderators:

Pär Alnhem, *President, Pharmadule, Inc.*

Dan Boyd, *Director of Engineering, Biogen Idec*

John Machulski, *Director of Engineering, Lonza Biopharmaceuticals*

Quality by Design: Integration of Research, Clinical and Process Development from Start to Finish

Co-moderators:

Anthony R. Mire-Sluis, Ph.D., *Head of Product Quality and External Affairs, Amgen Inc.*

Wassim Nashabeh, Ph.D., *Quality Control Clinical Director, Genentech, Inc.*

Single Use Processes

Co-moderators:

Russell Wong, Ph.D., *Senior Process Development Engineer, Biological Products, Bayer Healthcare*

Scott M. Wheelwright, Ph.D., *President, Strategic Manufacturing Worldwide*

10:00 *Poster/Exhibit Viewing and Networking Refreshment Break*

10:45 *Discussion Groups Resume*

12:00 **Technology Workshops**

Hear about the latest technologies directly from the developers.

Please see page 20 for workshop options and details.

12:30 *Luncheon, Poster and Exhibit Viewing*

Customize your afternoon schedule, choose from these sessions:

- **Media Development and Optimization** (*see pp. 13-14*)
- **Technology Transfer of Downstream Process** (*see p. 17-18*)
- **Site Tours to Genzyme or Applied Biosystems** (*see p. 3*)

Optional 4th Day

Choose the 4-day pass and profit from additional technical sessions. You can attend any of these sessions:

Cell Culture & Upstream Processing (*see pp. 14-15*)

- Process Characterization and Validation
- Post Approval Process Improvements
- How Upstream affects Downstream Processing

Recovery & Purification (*see pp. 18-19*)

- Streamlining of Rapid Process Development
- Worldwide Regulatory Implications for Recovery and Purification
- Transitions from Early to Late Phase to Commercial
- Emerging Applications for New Sensors and Process Control

Scientific Advisory Board

Richard Francis, *Director of Process Development and Technical Support, Protherics, United Kingdom*

Anthony R. Mire-Sluis, Ph.D., *Head of Product Quality and External Affairs, Amgen Inc.*

Tom Ransohoff, *Senior Consultant, BioProcess Technology Consultants*

Barry Rosenblatt, Ph.D., *Director, Technical Services, Charles River Laboratories, Inc.*

Charles Schmelzer, Ph.D., *Senior Scientist, Late Stage Purification, Genentech, Inc.*

Monday, September 19, 2005

7:30 *Registration and Coffee*

Regulatory Trends and Use of Comparability for Demonstrating Equivalence

8:30 Chairperson's Remarks

Chana Fuchs, Ph.D., *Expert Regulatory Biologist, Division of Monoclonal Antibodies, US FDA*

8:45 Comparability Exercise: European Position for Manufacturing Changes and for Biosimilar Products

Europe published its first guideline on comparability exercise in Sep. 2001, which addressed two situations: changes introduced in a manufacturing process and products claimed to be similar to others already marketed. Since then several steps forward have been accomplished, i) ICH Q5E harmonized the comparability exercise for process changes, ii) European framework defined a legal status for similar biological medicinal products, and iii) European guidelines for quality, safety and efficacy requirements are on the way to be finalized. An overview on these aspects is presented with special emphasis on quality requirements for "biosimilars."

Pierrette Zorzi, Ph.D., *Head, Department for Evaluation of Biological Products, AFSSAPS (French Regulatory Agency), France*

9:15 Demonstrating Comparability of Scaled-Up Processes: Examples of Successful Approaches

CASE STUDY

This talk presents filing strategies and outlines data packages used successfully for demonstration of process and product comparability. Selected case studies are presented to highlight the utility of different regulatory filing strategies, and to contrast differences in the extent of data included in each in order to demonstrate comparability.

Duane Bonam, Ph.D., *Principal Scientist, Manufacturing Sciences and Technology, Amgen, Inc.*

9:45 Challenges of Protein Biosimilarity with Transgenic Plants

CASE STUDY

In addition to possible modifications due to scaling-up, the impact of culture conditions in open fields has to be scrutinized. Taking recombinant lipase produced in transgenic corn as example, the talk shows encountered challenges, implemented solutions, the approach to demonstrate protein consistency and the first results obtained.

Dominique Mison, Ph.D., *Bio-Industrial Director, Meristem Therapeutics*

10:15 *Networking Refreshment Break*

10:45 Development and Application of a Cell Culture Manufacturing Platform: Approach to Scale-Up and Comparability

CASE STUDY

PDL has developed a robust manufacturing platform for humanized monoclonal antibodies based on murine NS0 cells, with harvest titers surpassing 2 g/L. In order to implement optimal commercial manufacturing processes, an integrated strategy is needed for process change, scale up, comparability assessment, and preclinical and clinical testing. Dr. Backer describes experience in migrating antibodies from three alternative expression systems to the NS0 cell culture platform.

Mark P. Backer, Ph.D., *Vice President, Technical Development, Protein Design Labs*

Biopharmaceutical Development

11:15 Rapid Development of a Therapeutic Monoclonal Antibody: From Benchtop to Clinic in Seven Months

CASE STUDY

A case study for streamlining and accelerating the drug development process is presented. Within seven months, we were able to prepare and test the MCB, develop a robust upstream process including development and implementation of an induction/fed-batch process which tripled the production yield, and generate the supporting characterization and pre-clinical data required for successful filing of an IND.

Lucille Chang, Ph.D., *Vice President, Manufacturing Operations, Raven biotechnologies, inc.*

11:45 Rational Development of a Cost-Effective Manufacturing Process for the Production of Rivax, a Ricin Vaccine

DOR BioPharma is developing a ricin vaccine based on a recombinant ricin toxin A (rRTA). Re-engineering of a low yielding and inefficient laboratory scale process at Cambrex has resulted in an increase in binding efficiency by a factor >25 fold. The rRTA manufacturing process will be reviewed with respect to a cost of goods approach in the context of a vaccine procurement program.

Christopher J. Dale, Ph.D., *Vice President, Technology, Cambrex Biopharmaceuticals*

Robert N. Brey, Ph.D., *Chief Science Officer, DOR BioPharma*

12:15 *Lunch on your own*

Scale-Down Technologies and Case Studies in Scaling Up

1:30 Chairperson's Remarks

Richard Francis, *Director of Process Development and Technical Support, Protherics, United Kingdom*

1:45 Use of Scale-Down Process Models for Scale-Up and Outer Limit Validation

CASE STUDY

The use of scale-down process models for determination of process control limits and optimization is becoming established practice. This presentation focuses on the actual use of approach for process optimization and yield / cost of goods improvement programs.

Richard Francis, *Director of Process Development and Technical Support, Protherics, United Kingdom*

2:15 Scale Down of Purification Unit Operations for Viral Clearance Studies

Viral clearance studies that comply with current regulatory expectations require that scale down models truly represent production. Details that are sometimes overlooked are discussed, and guidelines for scale down are presented.

Gail Sofer, M.S., *Director, Regulatory Compliance, GE Healthcare*

2:45 *Networking Refreshment Break*

3:15 **Development of a Scale-Translation Strategy for Efficient Scale-Up and Scale-Down of Commercial Cell Culture Processes** **CASE STUDY**

Efficient scale translation of a cell culture process is critical to ensure speed to market during development of new drug candidates. This presentation describes a guideline for approaching scale translation problems and gives specific recommended procedures for addressing these problems. Case studies include agitation scaling and qualification of a scale-down model for a recombinant protein product.

Benjamin Beneski, *Process Engineer, Amgen Inc.*

3:45 **Recovery Process Scale-Up of a Monoclonal Antibody for Early Clinical Development** **CASE STUDY**

Early development of a biological involves a trade off between minimizing effort on an unproven product and ensuring enough product characterization and purity to make certain that results are valid for your product. The effect of these trade offs on development will be presented as a case study detailing development of a monoclonal antibody from late stage research through phase II clinical trials.

Timothy Breece, *Senior Research Associate, Early Stage BioPharmaceutical Research, Genentech, Inc.*

4:15 *Brief Break for Room Change*

4:30 **Keynote Presentation**
Quality Partnerships – The Lowest Cost and Most Efficient “Carpool Lane” to Product Approval

Please see abstract on p. 3.

Ronald C. Branning, *Vice President, Commercial Quality, Genentech, Inc.*

5:15 **Keynote Presentation**
Building, Buying, Remodeling and Selling Biopharmaceutical Facilities: A Tale of Two Facilities

Please see abstract on p. 3.

H. Michael Koplove, Ph.D., *Vice President, Operations Network, Wyeth BioPharma*

6:00 **Exhibit Hall Opens with Networking Cocktail Reception**

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Learn about new technologies and services from over 80 exhibiting companies. Make new contacts while enjoying beverages and hors d'oeuvres. Learn new data from a large group of poster presentations.

Tuesday, September 20, 2005

7:00 *Registration and Coffee*

8:00 **Keynote Presentation**
Identification of Important Process Engineering Problems Requiring Joint Efforts of Biologists and Engineers

Please see abstract on p. 3.

Michael W. Glacken, Ph.D., *Senior Scientist II, Process Development, Millennium Pharmaceuticals, Inc.*

Cell Line Development and Clone Selection

8:45 **Chairperson's Opening Remarks**
Dan Allison, Ph.D., *Director, Production Development, ICOS Corporation*

9:00 **FACS Based Isolation of High Producing CHO Cells with Optimized Process Performance Using a Surface Capture Approach**

With the Single Cell Secretion Assay it is possible to measure the specific production rates of individual cells by catching secreted product in an artificial matrix applied to the cell surface. Flow cytometric cell sorting then allows to select rare cells with high production rates, which occur with frequencies as low as 10-6. We have taken advantage of the reduced work load required to select high producers by cell sorting, to include altered growth related production kinetics and stability of protein expression in the absence of selective pressure as additional selection parameters for cell line optimization.

Nicole Borth, Ph.D., *Professor, Department of Biotechnology, University of Bodenkultur, Austria*

9:30 **Approaches for High Throughput Screening**

The drive towards shorter process development timelines coupled with higher productivity expectations creates significant challenges for cell line development. This talk presents the current Wyeth BioPharma phase I/II clinical manufacturing cell line development paradigm, approaches to attaining high productivity lines, and compromises made in order to meet current timeline and project-throughput expectations.

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10:00 *Poster/Exhibit Viewing and Refreshment Break*

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We have developed a yeast-based protein production system capable of human-like N-glycosylation. We are now, in-house and in collaboration with biopharmaceutical companies, utilizing our control over N-glycosylation to influence tissue distribution and pharmacokinetics of therapeutic proteins. This knowledge will ultimately lead to the development of targeted drugs with increased potency.

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Automated cell imaging carried out on the novel LEAP™ system rapidly quantifies cell-specific antibody secretion rates for millions of cells grown on capture matrix plates. In situ laser-mediated purification then immediately clones highly-secreting cells, resulting in significant and stable improvement of antibody secretion in a high fraction of resulting sub-clones with in situ validated growth characteristics.

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The choice of a procedure to create a mammalian cell line is influenced by a number of factors including productivity, stability, cell line, cost and timelines. We have compared a traditional dhfr approach to one which utilizes a MAR, a genomic insulator. Data for GFP and a monoclonal antibody are presented.

Michael V. Murray, Ph.D., *Senior Scientist, Molecular Biology, Diosynth Biotechnology - a Akzo Nobel company*

12:00 **Technology Workshops**

Hear about the latest technologies directly from the developers. Please see page 20 for workshop options and details.

Tuesday, September 20, 2005 (continued)

12:30 Luncheon and Poster/Exhibit Viewing

Manufacturing Success Stories

2:00 **Chairperson's Remarks**

Howard L. Levine, Ph.D., *President, BioProcess Technology Consultants*

2:10 **HUMIRA™: Just In Time Manufacturing?**

CASE STUDY

HUMIRA™ (Adalimumab) is a fully human monoclonal antibody used for the treatment of rheumatoid arthritis. From the start of clinical development in 1997 and since market launch in 2003, a combination of facility expansions and process improvements was utilized to meet the increasing demand for this product, while trying to minimize the financial commitment at risk during the development cycle. This presentation illustrates the path taken, some of the resulting challenges and lessons learned.

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The rapid approval of Avastin by FDA was facilitated by Genentech's approach to the identification and confirmation of critical process parameters and the assessment and delineation of process monitoring and control points to assure product quality. This presentation includes the framework for process development, risk assessment and the use of PAT for process monitoring and control.

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S. Joseph Tarnowski, Ph.D., *Senior Vice President, Manufacturing Operations and Product Development, ImClone Systems Incorporated*

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Featured Presentation

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Current Practices and Future Directions in Bioprocessing

Please see abstract on p. 3.

Duncan Low, Ph.D., *Scientific Director, Process Development, Amgen, Inc.*

5:45-7:00 **Networking Cocktail Reception in Exhibit Hall**

Dedicated poster viewing from 6:00 - 7:00.

Wednesday, September 21, 2005

7:15 *Coffee and Breakfast Bakeries*

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8:10 **Chairperson's Remarks**

Laurel M. Donahue, Ph.D., *Manager, Technical Development, SAFC Pharma and*

Kathie S. Fritchman, *Senior BioProcess Specialist, BD Biopharm & Industry*

Process and Manufacturing Scale Up

8:30 **Steel vs. Bag: Comparison of Process Performance and Product Quality**

CASE STUDY

The Wave System 1000 is a disposable, self-contained bioreactor that is scalable to 500L. The system is designed for R&D, process development and GMP manufacturing. This presentation compares cell culture performance between the System1000 and large-scale stainless steel bioreactors using cell lines expressing clinical and commercially viable proteins. Case studies presented compare growth, metabolism, protein expression and product quality.

Bob Pendleton, *Scientist, Cell Science & Technology, Amgen, Inc.*

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A single-use stirred tank bioreactor system that is suitable for mammalian cell culture has been developed by Hyclone Laboratories, Inc., and Baxter Healthcare Corp. The scaleable mass-transfer characteristics of this bioreactor are described. Cell growth and metabolism data from batch cultures using a 250-liter prototype system are presented and compared to results from a traditional stainless steel bioreactor.

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CASE STUDY

Bioprocessors SimCell technology is evaluated against commonly used platforms for cell culture experimentation with emphasis on comparisons to shake flasks and bench top bioreactors. Cases studies of full and partial factorial cell culture experiments comprising several hundred independent cell cultures are also presented, demonstrating the high throughput and high data quality attainable with the SimCell system.

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Process scale-up may be defined as moving the process through gradual increases in scale and accuracy of scale-down models until the process is demonstrated to be ready for the final jump to commercial scale. This talk will describe a general strategy for scale-up of cell culture processes, including production and harvest steps. The use of scale-down models and other tools for scale-up are illustrated through case studies.

Douglas Miller, Ph.D., *Associate Director, Pilot Plant Operations, Amgen, Inc.*

Consider sending new colleagues in your group to "Scale-Up of Biological Processes for Rapid Introduction to Basic Principles" or "Technology Transfer 101"

See seminar insert or visit www.IBCLifeSciences.com/3124

11:00 Manufacturing Cost of Goods Analysis: Fed-Batch vs. Large Scale Perfusion

For a number of therapeutic protein targets, the nature of the product, its complexity, issues with stability, etc., 'drives' the selection of cell culture perfusion technology as the preferred upstream manufacturing route. This essentially eliminates fed-batch cell culture process technology from any assessment of manufacturing economics such as Cost of Goods (CoG) analysis. The rationale for making the decision between fed-batch and perfusion technology is examined together with an assessment of the impact of product titre on ultimate CoG for the manufacture of a monoclonal antibody product using a dedicated manufacturing facility based on either fed-batch or large scale perfusion technology.

Bo Kara, M.S., *Head of Expression and Cell Sciences, Avectia Biotechnology*

11:30 The ACE System: Engineering Artificial Chromosomes to Rapidly Generate High-Expressing Cell Lines for Manufacture of Recombinant Proteins

The ACE (Artificial Chromosome Expression) System is a unique satellite DNA-based expression system that uses pre-engineered artificial chromosomes with multiple recombination acceptor sites (Platform ACE) to allow for the transfer of single or multiple copies of genes into cells. Case studies will be presented where CHO cell lines expressing industry-relevant levels of antibody (>30 pg/cell/day) can be generated in less than 12 weeks without amplification. If available, data will also be provided on performance in small-scale bioreactors under optimized conditions.

Malcolm L. Kennard, Ph.D., *Director of Cell Line Engineering, Chromos*

12:00 Technology Workshops

Hear about the latest technologies directly from the developers. Please see page 20 for workshop options and details.

12:30 Luncheon and Poster/Exhibit Viewing

Customize your afternoon schedule, attend the session below on technology transfer or choose from the following:

- **Media Development and Optimization** (*see pp. 13-14*)
- **Site Tours to Genzyme or Applied Biosystems** (*see p. 3*)

The Good, The Bad and the Ugly...Technology Transfer of Downstream Processes

2:00 Learning from Technology Transfers – Case Studies from a Contractor's Perspective

CASE STUDY

Effective technology transfer is critical for the successful development and manufacture of Biologics. This presentation uses case studies to explore some of the issues that can arise in transfers between clients and contractors and between R&D and manufacturing. It describes approaches and risk-based tools that can be used to ensure success.

Mark A. Carver, Ph.D., *Head of R&D, Avectia Biologics, United Kingdom*

2:30 Internal Technology Transfer of Monoclonal Antibody Processes from California to Minnesota

CASE STUDY

Transfer of biopharmaceutical processes across sites can be a challenging objective. This talk will cover the evolution of PDL's technology transfer process for monoclonal antibodies. It will point out the key elements needed for a successful technology transfer, which has been learned through experience over the last fourteen years.

Karl Reindel, *Director, Process Development, Protein Design Labs, Inc.*

3:00 A Case Study for the Use of Laboratory Scale Techniques to Pack and Evaluate Production Scale Columns

CASE STUDY

The determination of proper column packing and test procedures prior to commercial production can reduce manufacturing costs and failures. Unique resin types justify the need to reinvestigate traditional methods for packing columns. We have developed a systematic approach for packing and evaluating columns at the laboratory scale. These parameters are resin type dependent, independent of column size and ensure long-term column stability.

Greg T. Runyon, Ph.D., *Senior Scientist, Purification Development, Diosynth Biotechnology*

3:30 Poster/Exhibit Viewing and Networking Refreshment Break

4:00 Technology Transfer from a Technology Project Manager's Perspective

CASE STUDY

A product and its production process are transferred between functional areas and facilities during development and commercialization. Processes are transferred from research to development, from process sciences to clinical or commercial manufacturing – within the same company or to a CMO – and between commercial manufacturing sites. This presentation will discuss aspects of technology transfer and the role of technology project managers in this process.

Joanne T. Beck, *Director, Biologics Program Management, Abbott Bioresearch Center*

4:30 Purification Scale-Up and Technology Transfer for Lonza Biologics 20,000L cGMP Facility

CASE STUDY

This presentation will focus on the challenges faced with simultaneous scale-up and tech transfer of mammalian cell culture processes from a CMO perspective. Emphasis will be placed on development techniques for rapid process evaluation to ensure facility fit. The mechanics for implementing and assessing process modifications will also be discussed.

David Page, *Process Development Engineer, Lonza Biologics*

5:00 Transfer of Altus's CLEC Process to a Japanese CMO

CASE STUDY

Altus Pharmaceuticals has developed a novel technology for delivery of therapeutic proteins. Drug delivery is based on proprietary and patented technologies for crystallization and cross-linking proteins (CLEC) to improve stability and increase concentration. This presentation will highlight some of the unique challenges encountered while transferring technology from the US to Japan. In addition to the obvious obstacles created by distance and language barriers, differences in business arrangements and project execution approaches creates additional challenges. The technical transfer approach for this program is contrasted with the approach typically used in the US and Europe.

Peter F. Levy, M.S., *Director, Process Development & Process Engineering, Technical Operations, Altus Pharmaceuticals, Inc.*

Optional 4th Day

Choose the 4-day pass and profit from additional technical sessions on Thursday. You can attend any of these sessions:

Cell Culture & Upstream Processing (*see pp. 14-15*)

- Process Characterization and Validation
- Post Approval Process Improvements
- How Upstream affects Downstream Processing

Recovery & Purification (*see pp. 18-19*)

- Streamlining of Rapid Process Development
- Worldwide Regulatory Implications for Recovery and Purification
- Transitions from Early to Late Phase to Commercial
- Emerging Applications for New Sensors and Process Control

Scientific Advisory Board

- Dan Allison, Ph.D.**, *Director, Production Development, ICOS Corporation*
- Laurel M. Donahue, Ph.D.**, *Manager, Technical Development, SAFC Pharma*
- Xuejun (Sherry) Gu, Ph.D.**, *Principal Research Scientist, Bioprocess R&D, Eli Lilly & Company*
- Charles Sardonini, Ph.D.**, *Research Scientist III, Process Development, Amgen, Inc.*
- Thomas Seewoester, Ph.D.**, *Associate Director, Process Development, Amgen, Inc.*
- Martin S. Sinacore, Ph.D.**, *Associate Director, Cell & Molecular Sciences, Wyeth BioPharma*
- Janani Swamy, Manager, Process Engineering/Development, BioEngineering, Genzyme**
- Ron Taticcek, Ph.D.**, *Associate Director, Fermentation MSAT, SSF Biochemical Manufacturing, Genentech, Inc.*
- Paul Wu, Ph.D.**, *Manager, Protein Isolation, Process and Technology Development, Bayer HealthCare*

Tuesday, September 20, 2005

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- 8:00 **Keynote Presentation**
Identification of Important Process Engineering Problems Requiring Joint Efforts of Biologists & Engineers
See abstract on p. 3.
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12:30 *Luncheon and Poster/Exhibit Viewing***Manufacturing Success Stories**2:00 **Chairperson's Remarks**

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12:30 Luncheon and Final Opportunity for Poster/Exhibit Viewing

Media Development and Optimization

2:00 Optimization of Media for Large-Scale Fed-Batch Cell Culture Manufacturing Processes

The integrated viable cell density and cellular productivity of a CHO fed-batch process can be maximized by appropriately modulating compositions of initial medium and feed solutions. For most nutrients, optimal concentrations in the bioreactor will be above the levels at which uptake is concentration-limited, but for certain nutrients, optimal concentrations will be lower in order to limit the generation of inhibitory metabolites.

Denis Drapeau, Ph.D., *Director, Bioreactor Process Development, Wyeth BioPharma*

Wednesday, September 21, 2005 (continued)

2:30 Hyper-Osmotic Shock – Manipulation of Cell Culture Media to Improve Productivity

Hyperosmotic stress has been widely shown to improve specific productivity in mammalian cell culture systems; however, the mechanisms of action remain unclear. We have employed a combination of transcriptional, translation, post-translational and genomic studies to elucidate these mechanisms. This presentation reports on these studies, possible regulatory bottlenecks, and strategies for cellular engineering and process design.

Susan Sharfstein, Ph.D., *Assistant Professor, Department of Chemical and Biological Engineering, Rensselaer Polytechnic Institute*

3:00 Cell Lines and Cell Culture: Risk Assessments and Current Testing Methodologies

Cells used to produce biopharmaceuticals may contain agents that negatively impact patient safety. There are also regulatory and business risks associated with the possible effects of these agents. Appropriate application of state-of-the-art testing methods can mitigate potential risks.

Gail Sofer, M.S., *Director, Regulatory Compliance, GE Healthcare*

3:30 *Poster/Exhibit Viewing and Networking Refreshment Break*

Product Quality

4:00 Integrating Product Quality into Process Development

In order to develop a commercially viable biotechnology process that ultimately meets product specification, it is increasingly important to assess product quality early on and apply the information as a feedback loop into process development. Examples of key product quality attributes and their integration into process development will be highlighted.

Stacey Ma, Ph.D., *Senior Scientist, Late Stage Analytical Development, Genentech, Inc.*

4:30 Development of a Cell Culture Process for Production of a Live Attenuated Chimeric Bovine Parainfluenza-Respiratory Syncytial Virus Vaccine **CASE STUDY**

Development of a live cell culture derived virus vaccine presents additional challenges to ensure quality of the clinical product. Development of a Chimeric Bovine Parainfluenza-Respiratory Syncytial (bPIV-RSV) viral vaccine is presented with discussion of regulatory hurdles, testing and qualification of the cell bank and clinical trial material.

Richard M. Schwartz, Ph.D., *Senior Director, Processing and Manufacturing Sciences, MedImmune Vaccines*

5:00 Environmental Effects on Product Quality – Approaches to Understanding and Controlling Glycosylation

In producing therapeutic proteins from cell culture processes, it is necessary to develop processes capable of delivering consistent protein characteristics, including glycosylation patterns. This presentation discusses approaches toward better understanding and control of recombinant protein glycosylation through environmental manipulations including medium composition and processing parameters.

Robert D. Kiss, Ph.D., *Principal Engineer, Late Stage Cell Culture, Process Development, Genentech, Inc.*

Consider sending scientists new to your group or business colleagues to “Upstream Processing 101” taught by Steven Chamow, Ph.D., Vice President, Process Sciences, Genitope Corporation.

See seminar insert or visit www.IBCLifeSciences.com/3124

Thursday, September 22, 2005

8:00 *Coffee*

8:30 Chairperson’s Opening Remarks

Ron Taticek, Ph.D., *Associate Director, Fermentation Manufacturing Sciences and Technology, Genentech, Inc.*

Process Characterization and Validation

8:45 Process Transfer and Scale-Up of Long-Term Cell Culture Processes: General Strategy and Lessons Learned

Process development and definition for therapeutics are typically performed at the pilot scale and are then rapidly scaled up to commercial scale. There are additional challenges presented by the transfer of long-term, micro carrier-based, perfusion processes. Strategies for successful technology transfer, demonstration of comparability, and scale-up from the pilot to commercial scale are discussed, with examples of some of the challenges encountered and lessons learned.

Claudia W. Buser, Ph.D., *Associate Director, BioEngineering, Genzyme Corporation*

9:15 Application of a Cell Culture Scale-Down Model to Process Validation and Post-Approval Changes **CASE STUDY**

A process validation strategy that uses a combination of data from a well-characterized cell culture scale-down model and data from a limited number of full scale runs will be presented. Case studies that used this approach to validate process changes to two commercial CHO processes will be highlighted.

Ron Taticek, Ph.D., *Associate Director, Fermentation Manufacturing Sciences and Technology, Genentech, Inc.*

9:45 *Networking Refreshment Break*

10:15 The Design and Application of Robustness Studies in Establishing Process Parameter Boundaries for Long-Term Microcarrier-Based Perfusion Cell Culture Processes **CASE STUDY**

The multi-phase nature of long-term cell culture processes requires consideration of the following during the design of robustness studies (1) changes in process parameter ranges across phases (2) the de-convolution of parameter interactions within and across phases and (3) the number and duration of experiments. Examples are presented to discuss (1) a paradigm for conducting such robustness studies (2) the application of Design-of-Experiments (DOE) for study design and (3) the application of these data in process definition.

Janani Swamy, M.S., *Process Engineering Manager, Bioengineering, Genzyme*

10:45 Flow Cytometric Cell Sorting: An Improved Method of Generating Single Cell Clones

Development of mammalian cell lines requires the use of cultures originating from a single cell. Limited dilution cloning, the traditional method of clonal generation, can less effectively assure one cell per well due to the propensity for cells to stick together and the error inherent in microscopic observation. Consequently, investigators commonly use 2 rounds of limited dilution cloning to ensure 95% confidence that a colony originated from a single cell. We have worked towards replacing the limiting dilution method with fluorescence activated cell sorting and have validated our instrument’s ability to accurately plate exactly 1cell/well and can achieve greater than 95% confidence in the clonal origin of our cells using just 1 round of sorting. The regulatory implications of using fluorescence activated cell sorting for single cell cloning will be discussed in this presentation.

Lara E. Krebs, M.S., *Assistant Senior Biologist, Bioprocess Fermentation Development, Eli Lilly and Company*

Post Approval Process Improvements

11:15 Rationale, Strategy and Issues with Cell Line Changes over the Product Lifecycle **CASE STUDY**

Biopharmaceutical development and manufacturing is subject to competing pressures to increase R&D speed and efficiency, while maximizing the eventual output of commercial processes. Wyeth BioPharma experience, data and perspective on the scientific and regulatory issues associated with cell line changes are discussed, with emphasis on how to balance economic realities against risk.

Timothy S. Charlebois, Ph.D., Director, Cell & Molecular Sciences, Wyeth BioPharma

11:45 Increasing the Process Yield and Efficiency in an Approved Commercial Manufacturing Facility for a Marketed Biologic **CASE STUDY**

Increasing the process efficiency of an approved biologic is subject to constraints that are not applicable to pre-clinical or phase I, II clinical process development. Significant process changes require equivalency testing and regulatory submissions before material made by the improved process can be released. This presentation will highlight post-approval process improvements for Amgen's Enbrel, that have resulted in improved process performance.

Charlie Sardonini, Ph.D., Senior Scientist, Process Development, Amgen, Inc.

12:15 Technology Workshop and Luncheon

Sponsored by  Life Sciences

Please see page 20 for workshop options and details.

How Upstream Affects Downstream Processing

2:00 Impact of Upstream on Downstream: Harvest Design for Optimum Overall Process Performance **CASE STUDY**

High product titer and cell density in cell culture can affect the performance of downstream purification. Careful development of the primary recovery operations yields an understanding of how cell culture quality influences purification. This knowledge is critical to ensure satisfactory and robust performance of the overall process.

Lars Pampel, Ph.D., Senior Scientist, Amgen, Inc.

2:30 How to Apply PAT in Upstream Process

The ultimate goal of implementing Process Analytical Technology (PAT) in any biological production process is to increase process understanding and reduce rejection rate by identifying the root cause in a timely manner. This presentation describes the success of a system for applying PAT in upstream process, where product quality attributes are not directly predictive of the downstream quality attributes. The system includes timely sampling, quick turn-around testing, comprehensive investigation, and proper implementation of corrective and preventive action.

Paul Wu, Ph.D., Manager, Protein Isolation, Process and Technology Development, Bayer HealthCare

3:00 Networking Refreshment Break

3:30 Impact of Cell Culture Conditions on Downstream Harvest/Clarification Operations

The productivity of cell culture processes has improved in recent years. While fed-batch culture titers have increased, so have the concentration of viable and non-viable cells as well as the amount of cellular debris. This talk will discuss the impact of "improved" cell culture processes on downstream harvest and clarification operations.

Jon Petrone, Principal Engineer, Purification Process Development, Wyeth BioPharma

4:00 The Effect and Extent of Cell Damage on Impurity Generation During the Primary Recovery Process

When a pharmaceutical process begins with mammalian cell culture, cell damage is a prominent concern, owing to the relative fragility of mammalian cells. During the primary recovery process, operational conditions can lead to increased cell damage, which in turn can lead to elevated levels of downstream host-cell impurity (HCI). A variety of operational parameters are characterized at the primary recovery stage to quantify the extent of cell damage and related downstream impurities. Ultimately, both capacity and quality of the recovery process are optimized.

Alexander J. Witz, Senior Process Development Scientist, Process Technology and Development, Bayer Healthcare

Optional 4th Day

Choose the 4-day pass and profit from strategic sessions on Monday. You can attend any of these sessions and the Monday evening keynotes:

- Strategic Planning for Efficient Manufacturing (p. 5)
- Current Drivers in Process Economics (p. 5)
- Regulatory Trends and Use of Comparability for Demonstrating Equivalence (p. 8)
- Biopharmaceutical Development (p. 8)
- Scale-Down Technologies and Case Studies in Scaling Up (pp. 8-9)

Poster Presentations

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- Posters will be displayed by conference module
- Dedicated poster viewing times scheduled in the exhibit hall
- 15 poster abstracts will be published in a special event preview
- Visit www.IBCLifeSciences.com/BPI/US for more information

We are currently accepting poster abstracts in the following topics:

- Cell Culture • Recovery & Purification • Production & Economics
- Scaling Up From Bench to Clinic

Sponsored by: 

Poster and Exhibit Viewing Hours

Monday, September 19, 2005	6:00 pm – 7:15 pm
Tuesday, September 20, 2005	10:15 am – 7:00 pm
Wednesday, September 21, 2005	9:45 am – 2:00 pm

Dedicated Poster Viewing

Tuesday, September 20, 2005	6:00 pm – 7:00 pm
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Poster presenters are asked to be at their posters during this time.

Poster Award Presentation

Wednesday, September 21, 2005	Before 10:00 am session break
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Abstracts submitted for poster presentations will be reviewed on the basis of scientific merit, novelty and practical application. All accepted poster abstracts will be included on the conference CD-ROM and in addition, abstracts of the highest relevance to bioprocessing research will be published in a special event preview. Poster presentations can not be used as exhibit displays or for marketing purposes. Poster abstracts must be submitted online at www.IBCLifeSciences.com/BPI/US. There is no fee to submit an abstract but presenters of accepted abstracts will be required to pay a \$50 poster board registration fee, in addition to conference registration fees. Size of the conference posterboard is 4'x8'w.

Scientific Advisory Board

Brian Kelley, Ph.D., Director, Purification Process Development, Wyeth BioPharma

Duncan Low, Ph.D., Scientific Director, Process Development, Amgen, Inc.

Joanne T. Beck, Ph.D., Director, Biologics Program Management, Abbott Bioresearch Center

Jill Myers, Ph.D., Senior Director, Process Sciences and Production, AME/Eli Lilly and Company

Tuesday, September 20, 2005

7:30 Registration and Coffee

8:00 Keynote Presentation

Identification of Important Process Engineering Problems Requiring Joint Efforts of Biologists & Engineers

Please see abstract on p. 3.

Michael W. Glacken, Ph.D., Associate Director, Process Development, Head, Biologics Process Development, Millennium Pharmaceuticals, Inc.

Optimizing Asset Utilization through Modeling and New Technologies

8:45 Chairperson's Remarks

Peter Latham, President, BioPharm Services US

9:00 Scheduling Models for De-bottlenecking and Throughput Analysis for Large-Scale Cell Culture Production

CASE STUDY

Scheduling models developed for two large-scale cell culture manufacturing facilities will be presented. The models were used to perform optimization and de-bottlenecking analysis at one facility, and process-fit and throughput analysis at another. The models have proven to be very useful tools for conceptual engineering, retrofitting and optimization.

Alex Fotopoulos, Associate Director, Engineering, Biogen Idec

9:30 Optimization of Manufacturing Operations Using Discrete Event Simulation

The presentation describes Avecia's experiences of optimizing multi product manufacturing operations, through use of modeling. The presentation assesses alternative capital and non-capital options, risk reduction when introducing new products and provides insight into human resource and plant constraints for different processes. Plans to improve operational effectiveness by integrating model use within the organization are also explained.

Bruce Williams, Manufacturing Technology Manager, Avecia Biotechnology, United Kingdom

10:00 Networking Refreshment Break with Exhibit and Poster Viewing

10:30 Capacity Utilization Modeling for Process Development Scheduling

CASE STUDY

Development groups frequently face multiple products, limited resources and tight timelines. To address these challenges, we have adapted a capacity utilization modeling platform to schedule and de-bottleneck drug development from cell line development to GMP production. This presentation describes the results of our modeling efforts.

Nicolina Hull-Campbell, Pharmaceutical Development Scientist, Xoma (US) LLC

11:00 The Use of Spreadsheet Process Modeling in Facility Design

Unither Pharmaceuticals was faced with the challenge of outsourcing or building manufacturing capacity. We used a spreadsheet model of our manufacturing process to evaluate this make-buy decision and to select an optimum process scale for our facility. This presentation analyzes how spreadsheet process modeling can be used to make informed decisions about manufacturing capacity and in facility design.

Jim Levin, D.V.M., Vice President, Manufacturing and Development, United Therapeutics Corp.

11:30 An Analysis of Single-Use Disposables Technology from an Experienced User's Perspective

Dr. Wong reports on technology development, requirements for implementation, facets of disposable assembly design and troubleshooting. Factors to consider in the decision to go to disposables are analyzed.

Russell Wong, Ph.D., Senior Process Development Engineer, Biological Products, Bayer Healthcare

12:00 Technology Workshops

Hear about the latest technologies directly from the developers. Please see page 20 for workshop options and details.

12:30 Luncheon and Poster/Exhibit Viewing

Manufacturing Success Stories

2:00 Chairperson's Remarks

Howard L. Levine, Ph.D., President, BioProcess Technology Consultants

2:10 HUMIRA™: Just In Time Manufacturing?

CASE STUDY

HUMIRA™ (Adalimumab) is a fully human monoclonal antibody used for the treatment of rheumatoid arthritis. From the start of clinical development in 1997 and since market launch in 2003, a combination of facility expansions and process improvements was utilized to meet the increasing demand for this product, while trying to minimize the financial commitment at risk during the development cycle. This presentation illustrates the path taken and some of the resulting challenges and lessons learned.

Peter F. Moesta, Ph.D., Divisional Vice President, Biologics Manufacturing, Global Pharmaceutical Operations, Abbott Bioresearch Center

2:40 Critical Process Parameters (CPP's) and System Design for Product Approval – Avastin™ Highlights

CASE STUDY

The rapid approval of Avastin™ by FDA was facilitated by Genentech's approach to the identification and confirmation of critical process parameters and the assessment and delineation of process monitoring and control points to assure product quality. This presentation will include the framework for process development, risk assessment and the use of PAT for process monitoring and control.

Ronald C. Branning, Vice President, Commercial Quality, Genentech, Inc.

3:10 The Second Erbitux® Plant: What Does a \$260 Million Investment Really Mean?

CASE STUDY

Erbitux® is a chimeric monoclonal antibody approved in the US and many European countries for treating refractory colorectal cancer patients. This presentation will review the status of the design, construction and costs of a second, multi-product production plant that will be used to produce Erbitux® and other products.

S. Joseph Tarnowski, Ph.D., Senior Vice President, Manufacturing Operations and Product Development, ImClone Systems Incorporated

3:40 Poster/Exhibit Viewing and Networking Refreshment Break

Featured Presentation

4:20 **Scaling Up and Transferring your Process: To Improve or Not Improve? That is the (Regulatory) Question**

It is an expectation that scale up will occur during the commercialization of biotechnology products, and this often involves the transfer of the process either within or between sites. There are regulatory requirements and expectations to assess comparability of both product and process. Making changes to the process at this stage requires a well designed strategy involving risk assessment, process characterization and monitoring and statistical data evaluation.

Anthony R. Mire-Sluis, Ph.D., *Head of Product Quality and External Affairs, Amgen, Inc.*

5:00 **Keynote Presentation**

Current Practices and Future Directions in Bioprocessing

Please see abstract on p. 3.

Duncan Low, Ph.D., *Scientific Director, Process Development, Amgen, Inc.*

5:45 **Networking Cocktail Reception in Exhibit Hall**

6:00-7:00 *Dedicated Poster Viewing*

Wednesday, September 21, 2005

7:15 *Coffee and Breakfast Pastries*

7:30 **Technology Workshop**

Hear about the latest technologies directly from the developers. Please see page 20 for workshop options and details.

8:00 **Keynote Presentation**

Protein Engineering in Biomedicine

Please see abstract on p. 3.

Karl Dane Wittrup, Ph.D., *J.R. Mares Professor, Chemical Engineering & Biological Engineering, Massachusetts Institute of Technology*

8:40 *Brief Break for Room Change*

8:50 **Chairperson's Remarks**

Joanne T. Beck, *Director, Biologics Program Management, Abbott Bioresearch Center*

Recovery Approaches

9:00 **Post-Refolding Harvest of *E. coli* Expressed Fc-fusion Proteins**

Refolding commonly involves solution conditions that interfere with precipitation or chromatography operations. Consequently, UF/DF is used for concentration and buffer exchange to decouple refolding from precipitation and subsequent chromatography. Successful development of these operations involves accepting compromises between yield, purity, media loading and time. The particular challenges associated with the post-refolding harvest of Fc-fusion proteins will be discussed.

Roger A. Hart, *Senior Principal Scientist, Amgen, Inc*

9:30 **Evolution and Scale-Up of Microfiltration of Antibody Purification**

A platform process has been developed for MAb purification utilizing microfiltration (MF) as the primary recovery step. The impact of cell culture conditions (cell line, batch vs. fed-batch) and MF operating parameters (crossflow rate, loading) has been evaluated to increase the yield and productivity for a range of diverse projects.

Sarah Parola, M.S., *Staff Chemical Engineer, BioPurification Development, Merck & Co., Inc.*

10:00 *Poster/Exhibit Viewing and Networking Refreshment Break*

10:30 **Lessons Learned: Recovery of MAb's from Low to High Density CHO Cell Cultures using Continuous Centrifugation**

Successful scalable primary recovery unit operations from bioreactor to harvest tank through a combination of centrifuge and filters requires experimentation with multiple factors. Studies with various g-force, flow rate and filter combinations produce different robust operating scenarios dependent upon different CHO cell fermentation conditions and recovery treatments. Scalability from bench to pilot to manufacturing scale has been successful.

David Bruton, Ph.D., *Manager, Process Sciences, Scale Up Lab, Abbott Bioresearch Center*

11:00 **Comparison of Different Harvest Approaches for Harvest of a Therapeutic Protein Product from High Cell Density Yeast Fermentation Broth**

CASE STUDY

This presenter will discuss two different approaches for harvesting an extra cellular therapeutic protein produced in high cell density fermentation: tangential microfiltration vs. continuous centrifugation followed by depth filtration. Results from the process development studies that were performed to identify optimal conditions for these approaches will be presented. Finally, a comparison of the cost of the different approaches will be presented, including an outline of the various attributes that impact the economics of performing the harvest unit operations.

Arurag S. Rathore, Ph.D., *Principal Engineer, Process Development, Amgen, Inc.*

11:30 **High Hydrostatic Pressure Disaggregation and Folding of Aggregated Recombinant Proteins: Examples and Production Costs Compared with Traditional Methods**

Protein aggregates reduce yields and increase cost at multiple stages of manufacturing. High Hydrostatic Pressure PreEMT™ technology has been demonstrated to be a novel, inexpensive and effective alternative to traditional methods of removing protein aggregates and increasing yields of correctly folded protein.

Lyndal Hesterberg, Ph.D., *President, BaroFold, Inc.*

12:00 **Technology Workshops**

Hear about the latest technologies directly from the developers. Please see page 20 for workshop options and details.

12:30 *Luncheon and Poster/Exhibit Viewing*

The Good, The Bad and the Ugly...Technology Transfer of Downstream Processes

2:00 **Learning from Technology Transfers – Case Studies from a Contractor's Perspective**

CASE STUDY

Effective technology transfer is critical for the successful development and manufacture of biologics. This presentation uses case studies to explore some of the issues that can arise in transfers between clients and contractors and between R&D and manufacturing. It describes approaches and risk-based tools that can be used to ensure success.

Mark A. Carver, Ph.D., *Head of R&D, Avecia Biologics, United Kingdom*

2:30 **Internal Technology Transfer of Monoclonal Antibody Processes from California to Minnesota**

CASE STUDY

Transfer of biopharmaceutical processes across sites can be a challenging objective. This talk will cover the evolution of PDL's technology transfer process for monoclonal antibodies. It will point out the key elements needed for a successful technology transfer, which has been learned through experience over the last fourteen years.

Karl Reindel, *Director, Process Development, Protein Design Labs, Inc.*

Wednesday, September 21, 2005 (continued)

3:00 **A Case Study for the Use of Laboratory Scale Techniques to Pack and Evaluate Production Scale Columns**

CASE STUDY

The determination of proper column packing and test procedures prior to commercial production can reduce manufacturing costs and failures. Unique resin types justify the need to reinvestigate traditional methods for packing columns. We have developed a systematic approach for packing and evaluating columns at the laboratory scale. These parameters are resin type dependent, independent of column size and ensure long-term column stability.

Greg T. Runyon, Ph.D., Senior Scientist, Purification Development, Diosynth Biotechnology

3:30 *Poster/Exhibit Viewing and Networking Refreshment Break*

4:00 **Technology Transfer from a Technology Project Manager's Perspective**

CASE STUDY

A product and its production process are transferred between functional areas and facilities during development and commercialization. Processes are transferred from research to development, from process sciences to clinical or commercial manufacturing – within the same company or to a CMO – and between commercial manufacturing sites. This presentation will discuss aspects of technology transfer and the role of technology project managers in this process.

Joanne T. Beck, Director, Biologics Program Management, Abbott Bioresearch Center

4:30 **Purification Scale-Up and Technology Transfer for Lonza Biologics 20,000L cGMP Facility**

CASE STUDY

This presentation will focus on the challenges faced with simultaneous scale-up and tech transfer of mammalian cell culture processes from a CMO perspective. Emphasis will be placed on development techniques for rapid process evaluation to ensure facility fit. The mechanics for implementing and assessing process modifications will also be discussed.

David Page, Process Development Engineer, Lonza Biologics

5:00 **Transfer of Altus's CLEC Process to a Japanese CMO**

CASE STUDY

Altus Pharmaceuticals has developed a novel technology for delivery of therapeutic proteins. Drug delivery is based on proprietary and patented technologies for crystallization and cross-linking proteins (CLEC) to improve stability and increase concentration. This presentation will highlight some of the unique challenges encountered while transferring technology from the US to Japan. In addition to the obvious obstacles created by distance and language barriers, differences in business arrangements and project execution approaches create additional challenges. The technical transfer approach for this program is contrasted with the approach typically used in the US and Europe.

Peter F. Levy, M.S., Director, Process Development & Process Engineering, Technical Operations, Altus Pharmaceuticals, Inc.

Thursday, September 22, 2005

7:30 *Coffee*

8:00 **Chairperson's Opening Remarks**

Brian Kelley, Ph.D., Director, Purification Process Development, Wyeth BioPharma

Streamlining of Rapid Process Development

8:15 **Processing of Polymer-Modified Proteins**

Modification of biopharmaceuticals with polymers such as poly(ethylene glycol) (PEG) can enhance their efficacy but may create a number of challenges related to their processing (Fee, C. J. and Van Alstine, J. M., *Chem. Eng. Sci.*, in press). This presentation will provide an introduction to PEG-protein chromatography and results obtained with promising new ion exchange media.

James M. Van Alstine, Ph.D., Professor, Staff Scientist, Protein Separations, GE Healthcare

8:45 **Application of High Throughput Screening to a Monoclonal Antibody Purification Platform**

Platform processes for MAb purification rely on multiple chromatography steps. Defining optimal chromatographic conditions may be accelerated using batch-binding studies in 96-well format. These high throughput screens evaluate combinations of excipients and pH, providing information on purity, yield and precipitation. A survey of MAbs suggests that minor modifications to a two column process may be sufficient for many antibodies.

Brian Kelley, Ph.D., Director, Purification Process Development, Wyeth BioPharma

9:15 **Novel Affinity Ligands for Biopharmaceutical Purification**

We have developed and commercialized a fully integrated solution to protein purification challenges using affinity ligands. Advances include enhanced specificity, "tunable" affinity, base stability, short development times, use of multiple matrices and ease of large scale non-animal derived production. Examples including the purification of IgG and Fab will be described.

Mark ten Haaft, Head of Ligand Development, The Biotechnology Application Centre, BV, The Netherlands

9:45 *Networking Refreshment Break*

10:15 **Enhanced Removal of DNA, Endotoxin and Leached Protein A from IgG Preparations with Ceramic Fluoroapatite and Hydroxyapatite**

Fluoroapatite and hydroxyapatite bind different biomolecules by different combinations of interactions with their phosphate and calcium residues. This study will demonstrate the relative contribution of each mechanism to the binding of IgG, protein A, DNA and endotoxin. It will then show how these mechanisms can be manipulated to enhance removal of these contaminants from IgG in the context of industrial purification processes.

Pete Gagnon, M.S., R&D Manager, Process Applications, Bio-Rad Laboratories

10:45 **Development of a Robust Clarification Process for MAb Purification**

CASE STUDY

Evolving highly productive cell culture processes pose significant challenges to the downstream clarification process. For example, larger depth filter surface areas are often needed, which lead to noticeable product loss and/or excess dilution. This presentation will discuss how novel devices and new depth filters as well as classic technologies such as filter aids and acid precipitation may be applied to accommodate challenging feed stocks.

Benjamin Roman, Senior Associate, Amgen, Inc.

Worldwide Regulatory Implications for Recovery and Purification

11:15 Current European Expectations for Viral Clearance

The current regulation for virus safety assessment of cell-derived products was laid down in the international guideline in 1997. There is a wide concurrence in the use and interpretation of the rules in the U.S. and Europe. Requirements for materials produced for clinical trials are under discussion in Europe at present. The presentation will cover aspects of viral clearance rules under discussion and focus on requirements for investigational medicinal products.

Hannelore Willkommen, Ph.D., Director, RBS Consulting

11:45 Regulatory Issues Affecting Purification Process Development

International regulations and evolving cGMPs governing production of recombinant protein therapeutics provide guidance on process validation, product purity and viral safety. These guidance documents influence the development of cGMP purification processes throughout the product lifecycle. Purification issues open to interpretation such as impurity targets, generic studies for viral clearance studies and resin lifetime validations will be discussed.

Heidi Reichert, Associate Director, Regulatory Affairs, Wyeth BioPharma

12:15 Technology Workshop and Luncheon

Sponsored by  Life Sciences

Please see p. 20 for workshop details.

Transitions from Early to Late Phase to Commercial

1:30 A Manufacturing Perspective of the Separation of Early and Late Stage Development

Process development for biopharmaceuticals is extremely complex and there are different manufacturing and process requirements for products as they proceed through development. To address this complex task, Genentech has implemented specialized process development functions for early stage products and late stage products. This presentation will discuss the advantages and challenges of this approach from manufacturing perspective.

Robert Caren, M.S., Senior Engineer, Manufacturing Science and Technology, Genentech, Inc.

2:00 Manufacture of a Novel Anti-Infective Protein in *E.coli* using Mixed-Mode Chromatography for Simple, Efficient and Cost Effective Manufacture

The use of mixed mode chromatography resin in conjunction with a charged flocculating agent to simplify and improve the recovery / capture of a novel recombinant anti-infective protein expressed in *E.coli* will be described. Although developed and marketed as an alternative to Protein A-based capture of antibodies, data will show that this resin (and other mixed mode resins) are also effective in the purification of non-antibody products.

Andy Topping, Ph.D., Early Phase Development Manager, Biologics, Avecia Biotechnology, United Kingdom

2:30 Qualification and Characterization of Scaled-down Purification Unit Operations

Scaled-down models for unit operations are an essential tool for the characterization and validation of biopharmaceutical manufacturing processes. It is vital from a compliance as well as from a business point of view that these models be qualified to be representative of the manufacturing process. DOE methods have been used to simultaneously qualify scaled-down unit operations, including chromatography and tangential filtration, and to characterize the influence of process parameters on product quality attributes.

Peter Wojciechowski, Director, Purification Sciences, Process Sciences, Global Biologics Supply Chain

3:00 *Networking Refreshment Break*

Emerging Applications for New Sensors and Process Control

3:30 New Sampling and Sensor Initiative (NeSSI) with Micro-Instrumentation for Process Analytical Technology (PAT)

Recent advances in miniaturization and sampling technology have improved measurement capabilities. Many micro-analytical developments are now being focused on the need for measurement tools to support the need for improved process monitoring. The use of micro-analytical tools combined with the emerging NeSSI platform will be described as a valuable approach for implementing PAT.

Mel Koch, Ph.D., Director, Center for Process Analytical Chemistry (CPAC), University of Washington

4:00 Monitoring and Troubleshooting of Biopharmaceutical Chromatography Operations

Automated chromatography operations generate large quantities of data from both on-line sensors and analytical testing. Monitoring, understanding and reducing variability in manufacturing necessitates improved methods for systematically detecting abnormalities and efficiently identifying underlying causes. This talk will outline some of the problems that can emerge in manufacturing operations and outline methodologies for leveraging historical process data in monitoring and troubleshooting.

Jack Prior, Ph.D., Director, Manufacturing Technical Support, Genzyme

Optional 4th Day

Choose the 4-day pass and profit from strategic sessions on Monday. You can attend the Monday evening keynotes and any of these sessions:

- **Strategic Planning for Efficient Manufacturing** (p. 5)
- **Current Drivers in Process Economics** (p. 5)
- **Regulatory Trends and Use of Comparability for Demonstrating Equivalence** (p. 8)
- **Biopharmaceutical Development** (p. 8)
- **Scale-Down Technologies and Case Studies in Scaling Up** (pp. 8-9)

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Consider sending new colleagues in your group to "Design and Validation of Downstream Unit Operations: The Basics" taught by Gail Sofer, Ph.D., GE Healthcare, and Anurag Rathore, Ph.D., Amgen, Inc.

See seminar insert or visit www.IBCLifeSciences.com/3124

Technology Workshops

Tuesday, September 20 • 12:00 PM

Single-use Aseptic Through-Wall Fluid Transfer

Sponsored by 

Sterile fluid transfer within or between facilities presents significant challenges. The single-use Rapid Aseptic Fluid Transfer (RAFT) system simplifies fluid transfer by eliminating cleaning and validation, while improving process security and product integrity. The RAFT system also holds the potential to reduce clean room space and the costs of building and operating bioprocessing plants.

Bob Smith-McCollum, Director of Marketing, Stedim

OR

Process Optimization and Intensification in Chromatography Scale-Up

Sponsored by 

Dr. Lyddiat describes contemporary approaches to the process optimization and intensification of chromatographic purification of protein products, which are designed to meet current challenges in the manufacture of biotherapeutics. The impact on capacity and throughput of solid phase properties and deployment, biochemical functionalization and design of operational cycles are discussed and illustrated with examples of enhanced process productivity.

Andy Lyddiat, Ph.D., Director R&D, Consett, U.K., Millipore Corporation

OR

Technology Workshop Presentation TBA

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Abstract and title not available at time of print. Please visit www.IBCLifeSciences.com/BPI/US for information as it becomes available.

Wednesday, September 21 • 7:30 AM

Process Development to Meet International Regulatory Requirements

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During the past two decades there has been a trend towards global harmonization of cGMP requirements. However, many unique requirements still remain in other countries relative to the U.S. industry standards. Understanding and addressing these differences early in the development process will minimize delays in the global commercialization timeline.

Roy Musil, Executive Director, Quality Assurance & Quality Control, Althea Technologies, Inc.

Wednesday, September 21 • 12:00 PM

Recent Advances in the Capture of Monoclonal Antibodies

GE Healthcare

Sponsored by 

Recent improvements in the upstream production of antibodies have increased the time-to-market and cost-efficiency pressures on the downstream processes. To address these needs GE Healthcare launched two new Protein-A media with improved capacity and life-length in January 2005: MabSelect Xtra and MabSelect SuRe. The features and benefits of these media will be presented including process economics analyses and application work.

Oguz Ersoy, Ph.D., Manager, Monoclonal Antibody Applications, GE Healthcare, Protein Separations

OR

Finding the Right Filter Combination – Essential Savings

Sponsored by 

Filtration is widely used within the biopharmaceutical industry to either clarify or sterilize drug products. However, filtration processes are frequently not optimized, resulting in yield losses, inefficient process schemes and excessive filtration costs. This technology workshop will discuss and present tools and techniques for filter train optimization.

Paul M. Priebe, Maik W. Jornitz

OR

Use of Rational Culture Medium Design™ to Rapidly Optimize Media for Two Recombinant CHO Cell Lines



Sponsored by  Grow With Us

Culture medium optimization can lead to dramatic increases in productivity of recombinant cell lines. When faced with limited time for media optimization, rigorous selection of methods and scales, and coordination and timeline management, are necessary for success. We have developed such methods and will show their application in a case study of medium optimization for two recombinant CHO cell lines.

Scott D. Storms, Ph.D. Senior Scientist and Group Leader, Industrial Cell Culture R&D, Irvine Scientific

Thursday, September 22 • 12:15 PM

Protein Purification

Sponsored by  Life Sciences

Comprehensively Chromatography - A Chromatography Workshop This workshop covers practical advice on selection criteria for chromatography techniques in protein processing and purification, including state-of-the-art rapid process optimization with a development case study. The theme of miniaturization continues with a discussion on methods to shrink time, space, labor and consumables use (buffers, eluants, regenerants, cleaning agents) in a full scale process of 10,000 liters or more. Finally, we discuss how modern chemistries can not only reduce COGS, but can fine-tune control over the purification of recombinant antibodies.

Speaker TBA

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INTERNATIONAL

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Tutorials for scientists and business professionals new to biotech:

- Process Scale-Up • Technology Transfer • Upstream Processing
- Downstream Processing • Intro to Biopharm Manufacturing Processes ... and more

See seminar insert or visit www.IBCLifeSciences.com/3124

Exhibit Hall

Exhibitor List as of May 11, 2005:

Althea Technologies, Inc • Applied Biosystems • Applikon Biotechnology
 • AppTec Biosystems • Asahi Kasei • ATMI Packaging • Avecia Biotechnology
 • Avid Bioservices, Inc. • Baxter Healthcare Corporation • BD BioPharm & Industry
 • BIOENGINEERING • Biomedical Resources International • BioPharm Services
 • BioProcessors Corporation • Bio-Rad Laboratories • BioReliance, invitrogen
 bioservices • Broadley-James Corp • Cambrex • Cardinal Health • Celliance
 • Charles River Laboratories • Clonex Development, Inc. • Cobra Biomanufacturing
 • Colder Products Company • Consolidated Polymer Technologies, Inc.
 • Corning, Inc. • CUNO Inc • Cytovance Biologics, Inc • Diosynth Biotechnology
 • Dowpharma • Drug & Market Development Publications • EMD Chemicals, Inc.
 • Formatech • GE Healthcare • GIBCO-An Invitrogen Company • HyClone
 • InterTech Science Park • Irvine Scientific • Ismatec SA • JRH Biosciences, inc.

Exhibit Hall Hours

Monday, September 19, 2005 6:00 pm – 7:15 pm

Tuesday, September 20, 2005 10:15 am – 7:00 pm

Wednesday, September 21, 2005 9:45 am – 2:00 pm

• KBI Biopharma • Kemp Biotechnologies, Inc. • Laureate Pharma, Inc.
 • Marcor Development Corporation • Mettler Toledo Ingold • Millipore
 Corporation • Nalge Nunc International • New Brunswick Scientific Co
 • Nova Biomedical • Novexin • One Cell Systems, Inc • optek-Danulat, Inc.
 • Pall Life Sciences • Pharmadule, Inc. • Prometic Biosciences, (USA) Inc.
 • SAFC • Sartorius Corporation • Sheffield Pharma Ingredients • Stedim, Inc./
 Integrated Biosystems • TC Tech Corporation • TechniKrom • Tekniscience, Inc.
 • Tosoh Bioscience, LLC • Wave Biotech, LLC • Westfalia Separator • YSI, Inc.

Sponsorship and Exhibition

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SAFC is your trusted source for all phases of biopharmaceutical development pharmaceutical, industrial development efforts and large-scale manufacturing needs. Our three business segments listed below provide world-class chemistry and biochemistry support at all levels of your development process.

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GE Healthcare



GE Healthcare provides transformational medical technologies that are shaping a new age of patient care. The protein separations group at GE Healthcare provides systems for biopharmaceutical manufacture and for laboratory-scale protein purification. Its protein separation solutions encompass both chromatographic and membrane separation technologies for all scales of operation. Visit www.proven-protein-purification.com for more information.



With over three decades of life-science innovation, Irvine Scientific provides superior industrial cell culture media products and custom media manufacturing for the biopharmaceutical industry. Our ongoing personal service, technical support and accessibility to our key team members ensures that your questions and concerns are addressed every step of the way. Our world-class cGMP facility was the first media manufacturing facility to receive ISO 13485:2003 certification. At Irvine Scientific our staff is virtually an extension of yours. Our objective is to become the supplier of choice for custom media formulations, optimization and contract manufacturing.



From drug development through pilot, to full-scale production, Millipore delivers quality tools and services; unmatched support; and innovative solutions for primary recovery, purification, concentration, viral clearance, aseptic processing, sterile filling and process monitoring (QA/QC). We offer expertise in processing biologics and classical pharmaceuticals, including recombinants, mAbs, proteins, vaccines, plasma, gene medicines and synthetic drugs. Visit us at www.millipore.com/biopharm and discover the more in Millipore.



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Technology Workshop Sponsors:



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Webcast Sponsors:



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Associate Sponsor/Luncheon Sponsor:



Pall offers process filtration, separation and purification development, pilot and manufacturing equipment and validation services together with pre-inspection reviews, troubleshooting consultancy, training, contamination analysis and other technical assistance. We offer protein expression monitoring and multi-step chromatography purification development, target and impurity tracking and host cell protein assay development, purification optimization and custom affinity sorbents.

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Interested in sponsorship or exhibiting opportunities?

Please contact: **Mike Washkowitz, Ph.D., Senior Business Development Manager**
Telephone: 508-614-1439 or 508-616-5550 x439
Email: mwashkowitz@ibcusa.com
Fax: 508-616-7950 or -5533

Visiting Boston and New England



For information on sightseeing activities and organized tours of Boston and the New England area, please contact the Boston Convention and Visitors Bureau at 1-888-SEE-BOSTON.

Discounted Hotel Reservations Information

IBC has allocated a block of rooms at four of Boston's outstanding hotels at special discounted rates. Please make your reservations as soon as possible as rooms tend to fill up quickly. All rates are subject to appropriate taxes. All reservations are subject to availability. Shuttle service will not be provided by IBC. Transportation information will be available on the BioProcess International™ web site and at www.AdvantageBOSTON.com.

The Seaport Hotel (*within walking distance to convention center*)

IBC discounted rate - \$225

One Seaport Lane, Boston, MA 02210

Phone: 617-385-4000 • Fax: 617-385-4001 • www.SeaportBoston.com

CUT-OFF DATE: August 24, 2005

Hyatt Harborside at Boston Logan Airport (*taxi ride to convention center*)

IBC discounted rate - \$249

101 Harborside Drive, Boston, MA 02128

Phone: 617-568-1234 • Fax: 617-567-8856 • www.Harborside.Hyatt.com

CUT-OFF DATE: August 22, 2005

The Hilton Boston Logan Airport (*taxi ride to convention center*)

IBC discounted rate - \$175

85 Terminal Road, Boston, MA 20218

Phone: 617-568-6700 • Fax: 617-568-6800 • www.Hilton.com

CUT-OFF DATE: August 24, 2005

Embassy Suites Boston at Logan Airport (*taxi ride to convention center*)

IBC discounted rate - \$175

207 Porter Street, Boston, MA 02128-2213

Phone: 617-567-5000 • Fax: 617-567-5999 • www.EmbassySuites.com

CUT-OFF DATE: August 24, 2005

The cut-off dates for discounted rates are firm. Reserve your room before the deadline to get the discounted rate. Be sure to mention IBC USA Conferences when making your reservation.

Airline Information

IMPORTANT INFORMATION REGARDING DISCOUNTED TRAVEL

RESERVATIONS: For discounted domestic and international air travel rates, please call IBC's official Air Travel Agency, Commonwealth Travel Advisors, (inside the U.S. call 508-366-3660 or 888-703-4286; outside the U.S. call 508-366-3660) and they can help you plan your travel via IBC's airline of choice, American Airlines. Please be certain to mention IBC along with the conference title, date and conference code 3097.

Registration Hours

Registration is located in the Registration East Lobby on Level 1, East next to the escalators.

Monday, September 19 7:30 am – 7:15 pm

Tuesday, September 20 7:30 am – 7:00 pm

Wednesday, September 21 7:15 am – 5:30 pm

Thursday, September 22 7:30 am – 4:30 pm

Boston Convention and Expo Center

Boston Convention and Expo Center
The Boston Convention & Exhibition Center
415 Summer Street, Boston, MA 02210

Phone: 617-954-2400 • www.AdvantageBOSTON.com

Transportation Information Available on the BioProcess International™ Conference Web Site – See the Transportation Section of the Left-Hand Navigation. Shuttle service will not be provided by IBC.

Parking is available at various surface lots throughout the area, all of which operate on a first-come, first-served basis. Maps and directions are also available at www.AdvantageBOSTON.com

Additional Registration Information

Unauthorized solicitation is strictly prohibited at this event and failure to comply could result in IBC revoking your access privileges. BioProcess International™ is a trade only event.

For your safety and security, a photo identification and industry related business card are required at the conference check-in to complete your registration.

Program content and speakers subject to change.

Onsite Check-in: ALL pre-registered attendees and on-site registrants will be required to check-in at the on-site registration counters in order to receive their conference badge and materials.

Dress attire: Business casual

Program content and speakers subject to change.

Children under 18 are not permitted in the exhibit hall under any circumstances.

Conference badges are non-transferable and lost badges will not be replaced without payment of the full conference registration fee.

Other Information: Main conference registration fee includes two luncheons, cocktail receptions, technology workshops, refreshments and CD ROM with speaker documentation supplied by the speakers. Please note that payment is required in advance of the conference. Please make check(s) (in U.S. funds drawn on a U.S. bank) payable to IBC USA Conferences and attach to the registration form. Confirmation of your booking will be sent. Should you elect to pay by MasterCard, Visa or American Express, please send your credit card number, expiration date, name as it appears on card and signature along with the registration form.

Substitutions/Cancellations: In order to receive a prompt refund, your notice of cancellation must be received in writing (by letter or fax) 10 working days before the conference. We regret cancellations will not be accepted after that date. However, we will be pleased to transfer your registration to another member of your company at any time. If you plan to send someone in your place, please notify us as soon as possible so that materials can be prepared. All cancellations will be subject to a \$195 processing fee. If IBC cancels an event, IBC is not responsible for any airfare, hotel or other costs incurred by registrants.

Data Protection: The personal information shown on this brochure, and/or provided by you, will be held on a database and may be shared with companies in the T&F Informa group in the UK and internationally. Sometimes your details may be obtained from, or made available to, external companies for marketing purposes. If you do not wish for your details to be used for this purpose, please email data-admin@ibcusa.com.

SPECIAL NEEDS: If you have special or dietary need(s), please let us know in order that we may address this for your attendance at this show. Please send your special needs via email at inquiry@ibcusa.com or fax 508-616-5522



BioProcess International™ World Conference & Exhibition Registration Form

5 Easy Ways to Register! **1. Phone – (508) 616-5550** **3. Email – reg@ibcusa.com**
2. Fax – (508) 616-5522 **4. Online – www.IBCLifeSciences.com/BPI/US**

5. Mail – IBC USA Conferences Inc.
One Research Drive, Suite 400A, P.O. Box 5195
Westborough, MA 01581-5195, U.S.A.

Step One: Please complete the following to register

3097 FAX

NAME 1 _____ JOB TITLE _____

NAME 2 _____ JOB TITLE _____

NAME 3 – **FREE 3rd Registration** (see GROUP RATE below) _____ JOB TITLE _____

E-MAIL Yes, I would like to receive occasional e-mail messages and offers from other organizations.

ORGANIZATION _____ DEPARTMENT _____

MAILING ADDRESS _____

CITY _____

STATE _____ POSTAL CODE COUNTRY _____

TELEPHONE _____ FAX _____

Step Two: Please select main conference package

A. Choose One Conference Package Below (*Exhibit Hall included; open Mon.-Wed.:*)

	Commercial	Academic/Govt.*
4-Day Pass	<input type="checkbox"/> \$1899	<input type="checkbox"/> \$899
3-Day Pass (Monday - Wednesday)	<input type="checkbox"/> \$1599	<input type="checkbox"/> \$699
3-Day Pass (Tuesday-Thursday)	<input type="checkbox"/> \$1599	<input type="checkbox"/> \$699

*Academic rate is extended to full-time employees of government, universities & university-affiliated hospitals only.
 3-Day and 4-Day passes include a CD-ROM of submitted speaker slides from all 4 modules.

Additional:

- Please check if you would like to subscribe to the BioProcess International™ magazine.
- Please check if you would like to receive the official conference newsletter – BioProcess International™ Conference Chronicles (be sure to provide your email address above)

GROUP RATE: Register 2 and the 3rd attends for FREE. Lesser registration fee will be deducted. Submit all registrations concurrently to receive discount.

Unable to Attend? Purchase the Conference CD-ROM. This comprehensive selection of bound "hot off the press" information will be available two weeks after the conference.
 I cannot attend. Please send _____ CD-ROM(s). Enclosed is my payment for \$399 each, plus shipping and handling (\$25 in the U.S., \$45 outside the U.S.).

Step Three: Site tours

Please specify which site you would like to visit (details p. 3):

- Applied Biosystems** - open to 75 People
- Genzyme** - open to 40 People

You must register for a 3- or 4-day pass and select your tour by August 22. Space is available on a first-come, first-served basis and is very limited. We will notify you by August 29 if you will be attending the tour.

Step Four: Poster presentations

Do you wish to present a poster? Yes No

For Conference Attendees who have selected a package above \$50 FREE
 Please submit poster abstract online at www.IBCLifeSciences.com/BPI/US by June 17, 2005 for review in the show preview, or August 19 for inclusion on the conference CD-ROM. (All posters must be approved by Poster Review Committee).

Step Five: Please select primary conference topic you will attend

A. Please select the primary conference module you will attend (even if you have selected the 4-day pass): Your conference pass allows you to switch between modules on days you are registered, and you will receive documentation from all modules on the CD-ROM.

- Production & Economics** (Monday - Wednesday)
- Scaling Up from Bench to Clinic** (Monday - Wednesday)
- Cell Culture & Upstream Processing** (Tuesday-Thursday)
- Recovery & Purification** (Tuesday-Thursday)

Step Six: Please tell us more about you

1. Which category best describes your primary Job Title? (please check only one)

- | | |
|--|--|
| 1001 <input type="checkbox"/> Academic Dept. Head/Chair | 1012 <input type="checkbox"/> Licensing Director/Manager |
| 1002 <input type="checkbox"/> Business Development | 1013 <input type="checkbox"/> Marketing/Market Analyst/Sales |
| 1003 <input type="checkbox"/> CEO/COO/President/Executive | 1014 <input type="checkbox"/> Post Doc. Fellow/Ph.D. Candidate/Student |
| 1004 <input type="checkbox"/> CIO/VP/Director of Information Systems | 1015 <input type="checkbox"/> Principal Investigator |
| 1005 <input type="checkbox"/> Consultant | 1016 <input type="checkbox"/> Process Engineer |
| 1006 <input type="checkbox"/> Chief Financial Officer/VP/Director of Finance | 1017 <input type="checkbox"/> Professor/Instructor |
| 1007 <input type="checkbox"/> Group Leader/Project Manager | 1019 <input type="checkbox"/> Research Assistant/Associate |
| 1008 <input type="checkbox"/> Engineer/Technology Analyst | 1020 <input type="checkbox"/> Research Director/VP of Research |
| 1009 <input type="checkbox"/> Financial/Investment Analyst | 1021 <input type="checkbox"/> Research Scientist |
| 1010 <input type="checkbox"/> Lab Director/Lab Manager/Dept. Manager | 1022 <input type="checkbox"/> Other (please specify) _____ |
| 1011 <input type="checkbox"/> Lawyer/Legal Affairs | |

2. Which category best describes your Business/Industry? (please check only one)

- | | |
|---|--|
| 2001 <input type="checkbox"/> Biopharmaceutical Company | 2010 <input type="checkbox"/> Law Firm |
| 2003 <input type="checkbox"/> Consulting Firm/Organization | 2011 <input type="checkbox"/> Market Analysis Company |
| 2004 <input type="checkbox"/> Clinical/Contract Research Organization | 2012 <input type="checkbox"/> Pharmaceutical Company |
| 2005 <input type="checkbox"/> Government Agency/Laboratory | 2013 <input type="checkbox"/> Publishing (Media) |
| 2006 <input type="checkbox"/> Hospital/Medical Center | 2014 <input type="checkbox"/> University/Academic |
| 2007 <input type="checkbox"/> Independent Laboratory | 2015 <input type="checkbox"/> Other (please specify) _____ |
| 2008 <input type="checkbox"/> Instrument/System Manufacturer | |
| 2009 <input type="checkbox"/> Financial/Investment Institution | |

3. Which category best describes your Field/Discipline? (please check only one)

- | | |
|---|--|
| 3001 <input type="checkbox"/> Bioanalytical Chemistry | 3013 <input type="checkbox"/> Medicinal/Organic Chemistry |
| 3002 <input type="checkbox"/> Biochemistry | 3014 <input type="checkbox"/> Molecular Biology/Microbiology/Cell Biology |
| 3003 <input type="checkbox"/> Bioengineering | 3015 <input type="checkbox"/> Neuroscience |
| 3004 <input type="checkbox"/> Bioinformatics/Informatics | 3017 <input type="checkbox"/> Pharmacology |
| 3005 <input type="checkbox"/> Business (Financial/Legal/Marketing) | 3019 <input type="checkbox"/> Process Development |
| 3024 <input type="checkbox"/> Business Strategy & Partnering | 3025 <input type="checkbox"/> Protein Therapeutics |
| 3006 <input type="checkbox"/> Clinical Diagnostics | 3020 <input type="checkbox"/> Proteomics/Protein Science/Protein Chemistry |
| 3007 <input type="checkbox"/> Combinatorial Chem/Computational Chem | 3021 <input type="checkbox"/> Screening/Assay Development |
| 3008 <input type="checkbox"/> Drug Development | 3026 <input type="checkbox"/> Systems Biology |
| 3009 <input type="checkbox"/> Engineering/Programming | 3027 <input type="checkbox"/> Toxicology |
| 3010 <input type="checkbox"/> Genomics/Genetics | 3022 <input type="checkbox"/> Virology |
| 3011 <input type="checkbox"/> Immunology | 3023 <input type="checkbox"/> Other (please specify) _____ |
| 3024 <input type="checkbox"/> Information Management/Science | |
| 3012 <input type="checkbox"/> Lead Discovery | |

4. Please indicate your role in the purchasing/contracting of products and services (please check only one)

- 4001 I have final approval/make the final decision
- 4002 I make the final recommendation
- 4003 I am part of the recommendation process
- 4004 I have no role in purchasing/contracting decisions

5. Please indicate your company's/department gross revenue for the last fiscal year – a rough estimate is sufficient (please check only one)

- | | |
|---|--|
| 5001 <input type="checkbox"/> Under \$500,000 | 5006 <input type="checkbox"/> \$25 million - \$50 million |
| 5002 <input type="checkbox"/> \$500,000 - \$999,000 | 5007 <input type="checkbox"/> \$50 million - \$100 million |
| 5003 <input type="checkbox"/> \$1 million - \$5 million | 5008 <input type="checkbox"/> \$100 million - 1 billion |
| 5004 <input type="checkbox"/> \$5million - \$10 million | 5009 <input type="checkbox"/> Over \$1 billion |
| 5005 <input type="checkbox"/> \$10 million - \$25 million | |

6. Please indicate the number of employees in your company? (please check only one)

- | | |
|---|---|
| 6001 <input type="checkbox"/> Under 10 | 6005 <input type="checkbox"/> 1000 – 5000 |
| 6002 <input type="checkbox"/> 10 - 99 | 6004 <input type="checkbox"/> 250 – 999 |
| 6003 <input type="checkbox"/> 100 – 249 | 6006 <input type="checkbox"/> Over 5000 |

Step Seven: Payment Information

Payment is required in advance of the conference

Mastercard Visa American Express Check Wire Transfer

Total: \$ _____ For on-site registrations, please add \$100

Please make check(s) (in U.S. funds drawn on a U.S. bank) payable to IBC USA Conferences and attach to the registration form. Confirmation of your booking will be sent. Wire Transfer: Please tell your bank to include the conference code 3097, invoice number, person attending, name and date of the conference in the transfer instructions. Transfers should be made to Fleet Bank NA, 1185 Ave. of the Americas, 3rd Fl., New York, N.Y. 10036. Account No. 9417201626, Routing No. 021200339.

Card # _____ Exp. Date _____

Name (as appears on card) _____

Signature _____