THE Meeting Place for the Bioprocessing Industry

The most highly respected, well-attended industry event for biopharmaceutical process development and manufacturing

BioProcess™ INTERNATIONAL

CONFERENCE & EXHIBITION

Conference: November 6-9 • *Exhibition:* November 6-8 • San Francisco Hilton • San Francisco, CA, USA

Featuring Four Tracks:

1 Production & Economics of Biopharmaceuticals

- ***NEW!*** **Three-hour workshop-style audience interactive discussion** on **Quality by Design** featuring moderators and panelists from **US FDA, Amgen, Biogen Idec, Bristol-Myers Squibb** and **Genentech**
- Achieve **greater operational efficiency** by hearing new reports from **Baxter, Wyeth BioPharma, Genentech, Abbott** and **Amgen**
- Increase your bottom line and net present value with **flexible capacity and facility planning** and **cost forecasting techniques** from **Bristol-Myers Squibb, Pfizer** and **Genentech**
- Understand the **economics of regulatory compliance** through insights from **Stryker Biotech, Genentech** and **Biogen Idec**

2 Scaling Up from Bench through Commercialization

- ***NEW!*** Session on **regulatory trends** including reports from Chris Joneckis of **CBER, FDA**, Hannelore Willkommen of RBS Consulting on the New Clinical Trial Material Requirements in Europe, insights from Carolyn Renshaw of **OCBQ, CBER, FDA** and **case studies** from Richard Francis of **Protherics** and Alain Bernard of **Serono**
- Learn process engineering tips to reduce steps, save time and lower developmental costs while still ensuring quality. Novel harvest technologies and platform case studies from **Amgen, Raven biotechnologies, Lonza, Biogen Idec,** and **Human Genome Sciences**
- Speed your **scale-up and comparability programs** with examples from **Merck, Novartis** and **Amgen**

3 Cell Culture & Upstream Processing

- ***NEW!*** Session on **large scale process troubleshooting**, featuring **case studies** from **Centocor, Wyeth** and **Genentech**
- **Achieving 5 g/L –** Learn how **Lonza** has optimized cell lines and culture conditions for increased productivity of recombinant antibodies
- Hear a **Wyeth** case study that reveals **striking conclusions from detailed analysis of genetic, epigenetic and phenotypic variation** in cell populations during development
- Learn how **Amgen** is **increasing understanding for legacy cell culture products** and **determining how small you can go with scale down models**

4 Recovery & Purification

- ***NEW!*** Session on **Recovery and Purification from High Titer Feedstocks,** including **Medarex** on **high titer cell culture processes with highly efficient purification process for Hu Mabs** and **scale-dependant impact of cell culture on recovery performance** from **Amgen**
- Hear how **Lonza** has **adapted downstream purification of monoclonal antibodies to meet the challenges of high-titer cell culture processes** without radically changing their technology base
- Learn how to achieve a successful biotech process technology transfer with examples from **Biogen Idec, Genentech, Micromet AG,** and **Wyeth**

Photos provided by Cambrex, Diosynth, Millipore & West Pharmaceuticals.

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Founding Publication

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The Most Comprehensive In-Depth Conference Program for the Industry

1 IBC's 12th International Production & Economics of Biopharmaceuticals

As the biopharmaceutical industry matures, enormous opportunities arise to streamline processes, save time and money, forecast costs more efficiently, and plan for capacity in a flexible manner. Lean manufacturing, six sigma and related strategies borrowed from other industries are being adapted and implemented in bioprocessing in order to achieve significant reductions in costs while fostering employee satisfaction and retention.

This conference track allows you to benchmark your efforts in improving operational efficiencies against the leading large biopharma companies as well as smaller organizations with cutting-edge strategies. From companies including Stryker Biotech and Human Genome Sciences to Genentech's Vacaville and Wyeth, gain valuable tips to enhance your company's programs.

2 IBC's 10th International Scaling Up from Bench through Commercialization

In the race to first-in-humans or first-to-market, companies strive to find a balance between the need for speed and the potential cost savings of taking the time to develop a truly robust process. New questions are arising about the meaning of "design space" and the relationship between scale down models and actual performance in commercial scale process.

In this conference track learn insights from FDA and a former European regulator on requirements for clinical trial material in US and Europe. Hear tips on how to relate scale down to scale up and comparability strategies from companies ranging from Protherics and Raven to Merck, Novartis and Serono. Hear practical applications of new technologies from Lonza and Biogen Idec. Gain Amgen's perspective on understanding protein aggregation, and platform technology case studies from Genentech and Human Genome Sciences.

3 IBC's 7th International Cell Culture & Upstream Processing

The revolution in upstream processing has been fueled by a variety of new technologies, including high-throughput screening and the use of both analytical chemistry and genomic data to deliver higher yields of consistent quality product. Driving expression levels to unprecedented yields are a combination of advances in cell line engineering, clone screening and selection, and medium development with successful process development and optimization strategies to optimize production.

This conference track brings together academic and industry leaders who will report on the latest advances during every stage of the process from molecular biology through manufacturing at commercial scale. Case studies have been carefully selected that ensure efficient and successful cell culture processes and their impact on downstream process performance.

4 IBC's 8th International Recovery & Purification

The seemingly relentless increase in expression levels from advances in cell culture present significant challenges for the biotech industry to maximize downstream operations to maintain pace with rising titers. This need to accommodate higher expression levels calls for new approaches to recovery and purification by employing new technologies and techniques while developing more efficient and economical downstream process strategies.

This conference track focuses on the evolution in downstream processing and how thought leaders in the industry are developing and implementing new technologies while optimizing processes and productivity. Case studies from industry leaders including Amgen, Genentech, Johnson & Johnson, Lonza, and Merck will help you improve process efficiencies to meet the demand created by the upstream revolution.

The Largest Array of New Products, Technologies and Services in Biopharmaceutical Production – Over 80 Companies Exhibiting

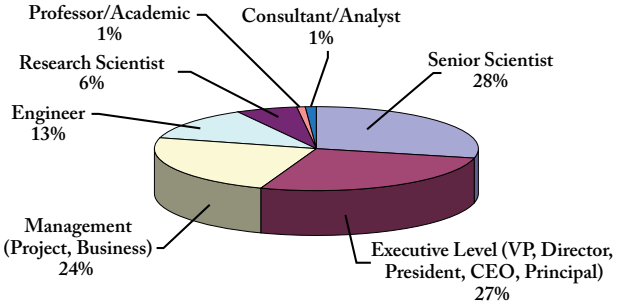
IBC's BioProcess International™ Conference and Exhibition features the most extensive exhibit hall dedicated *exclusively* to suppliers to biopharm manufacturers, along with poster presenters in applied bioprocess research. Supplement your learning in the conference sessions with conversations and demonstrations from the leading product and service providers. Discuss cutting-edge research with poster presenters during the dedicated poster viewing time featured on the exhibit floor.

Superior Networking – Over 1,000 Participants Expected

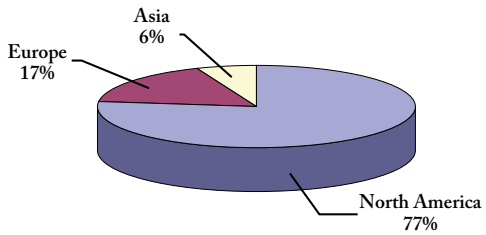
Last year over 1000 strategic planners, process scientists and engineers, heads of manufacturing and operations, and upstream and downstream processing specialists took part in BioProcess International™ Conference and Exhibition in Boston. Take advantage of ***THE*** networking event in the biopharmaceutical production industry.

Profile of Attendees from BioProcess International™ Conference and Exhibition 2005

Job Functions



Geographic Regions



Keynote Presentations

Improving FDA Regulation of Product Quality

CDER remains committed to the goals of FDA's Pharmaceutical Quality Initiative for the 21st Century and to improving policies and practices for submitting and reviewing chemistry manufacturing and control (CMC) information. This initiative sets forth a systematic approach to regulating pharmaceutical quality to ensure predictability, consistency and overall effectiveness of the regulatory processes. I will highlight the specific changes which have taken place as a result of the initiative and will provide participants with an opportunity to become better acquainted with how these changes will relate to pharmaceutical manufacturing practices in the future.

Jon E. Clark, Ph.D., *Associate Director for Policy Development and GMP, Office of Pharmaceutical Science, Center for Drug Evaluation and Research,* **U.S. Food and Drug Administration**

Implementation of Quality by Design in Biotechnology Product Development: Industry Perspective

FDA recently released guidance discussing its expectations for Quality by Design (QBD). How QBD can be implemented in the biotech industry remains a topic for discussion and implementation. Issues regarding how to balance additional product and process characterization, design of experiments, PAT and other QBD tools without hampering development timelines needs to be addressed. Also, there are specific areas in drug development where QBD has most relevance and this needs to be built into a structured product development and commercialization program.

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

Using Bioprocess Manufacturing as a Strategic Advantage

Treating manufacturing as "capital and operating expenses to be avoided" can be a costly mistake. For many biopharmaceutical products, developing or selecting the most appropriate manufacturing technology and making solid strategic decisions regarding investment timing, sourcing, and capacity are critical to the successful launch of a new product. Along with these decisions, management of project risk, manufacturing learning curves, and process improvements can more than double potential project value.

Brett L. Schmidli, *President,* **Schmidli & Associates;** *former Senior Vice President, Technical Operations,* **PDL BioPharma, Inc.**

Operational Excellence – Achieving World Class Performance

Achieving world class performance through an effective operational excellence program is not just about the tools but also about a change in the culture. Genentech is experiencing the most expansive growth phase in the company's 30-year history. Mr. Moore will share his experience and approach in effectively driving an operational excellence program which links the company's objectives to the production shop floor through the use of operational excellence tools that drive culture change to achieve unparalleled results.

Tim Moore, *Vice President of South San Francisco Manufacturing Operations,* **Genentech, Inc.**

With Special Thanks to the Scientific Advisory Boards

Production and Economics

Uwe Buecheler, Ph.D., *Managing Director, Biopharmaceuticals/Site Management,* **Boehringer Ingelheim Pharma GmbH & Co. KG,** *Germany*

Parrish M. Galliher, *President and CTO,* **Xcellerex Inc.**

Frank Jackson, *Vice President,* **Genentech Vacaville Product Operations**

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

Michael D. Kowolenko, Ph.D., *Senior Vice President, Pharmaceutical Operations & Technology,* **Biogen Idec**

Peter F. Moesta, Ph.D., *Divisional Vice President, Biologics Manufacturing,* **Abbott Bioresearch Center**

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

Scaling Up from Bench through Commercialization

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

Daotian Fu, Ph.D., *Senior Director of Bioanalytical Development,* **Genzyme Corporation**

Dr. Günter Jagschies, *Director R&D, Customer Applications, Protein Separations,* **GE Healthcare Bio-Sciences,** *Sweden*

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

Rhona O'Leary, Ph.D., *Director, BioProcess Development,* **Genentech, Inc.**

Tom Ransohoff, *Senior Consultant,* **BioProcess Technology Consultants, Inc.**

Cell Culture and Upstream Processing

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

Laurie Donahue-Hjelle, Ph.D., *Technical Manager,* **SAFC Biosciences**

Xuejun "Sherry" Gu, Ph.D., *Principal Research Scientist, Bioprocess R&D,* **Eli Lilly & Company**

Charles Sardonini, Ph.D., *Research Scientist, Manufacturing Sciences and Technology,* **Amgen Inc.**

Janani Swami, Ph.D., *Associate Director, Cell Culture Operations, Allston Landing,* **Genzyme**

Ron Taticek, Ph.D., *Associate Director, Fermentation MSAT, SSF Biochemical Manufacturing,* **Genentech, Inc.**

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

Recovery and Purification

Joanne Beck, Ph.D., *Director of Biologics Manufacturing,* **Abbott Bioresearch Center**

Uwe Gottschalk, Ph.D., *Vice President, Purification Technology,* **Sartorius AG,** *Germany*

David W. Kahn, Ph.D., *Director, Late-Stage Purification Development,* **Human Genome Sciences, Inc.**

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

Jill A. Myers, Ph.D., *Principal Consultant,* **BioPro Consulting**

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

Peter Wojciechowski, *Director, Purification Technology, Global Biologics Supply Chain,* **Johnson and Johnson**

Conference-At-A-Glance

Register for the 4-Day Pass
to attend Monday's strategic level sessions and Thursday's in-depth scientific sessions

Customize Your Agenda ... Your registration gives you access to all four tracks

Monday, November 6, 2006 — *Exhibit Hall Opens 5:30 pm - 7:00 pm*

	Production & Economics of Biopharmaceuticals	Scaling Up from Bench through Commercialization
8:00 am - 11:45 am	Achieving Operational Efficiences	Smart Process Engineering to Save Time, Money and Ensure Quality
11:45 am - 12:15 pm	*Technology Workshops sponsored by Stedim Biosystems and Millipore Corporation*	
1:45 pm - 3:30 pm	Effects of Regulatory Requirements on Economics	Comparability Strategies to Support Process Changes throughout Development
4:00 pm - 5:30 pm	*Keynote Presentations:* **Using Bioprocess Manufacturing as a Strategic Advantage** **Brett L. Schmidli,** *President,* **Schmidli & Associates;** *former Senior Vice President, Technical Operations,* **PDL BioPharma, Inc.** **Operational Excellence – Achieving World Class Performance** **Tim Moore,** *Vice President of South San Francisco Manufacturing Operations,* **Genentech, Inc.**	
5:30 pm -7:00 pm	*Exhibit Hall Opens with Cocktail Reception Sponsored by* SAFC Biosciences™ Accelerate Success™	

Tuesday, November 7, 2006 — *Exhibit Hall Hours: 9:45 am - 7:15 pm*

	Production & Economics of Biopharmaceuticals	Scaling Up	Cell Culture	Recovery and Purification
8:00 am - 12:00 pm	Facilities and Flexible Capacity Planning	Regulatory Trends Impacting Biopharmaceutical Manufacturing and Scale Up		Applying Novel Process Technologies
12:00 pm - 12:30 pm	*Technology Workshops Sponsored by BD Biopharm & Industry, Irvine Scientific and Sartorius*			
12:30 pm - 2:00 pm	Networking Luncheon in Exhibit/Poster Hall with Roundtable Discussions			
2:00 pm - 3:45 pm	Featured Case Studies in Successful Scale-Up and Cost Savings			
4:15 pm - 5:45 pm	*Keynote Presentations:* **Improving FDA Regulation of Product Quality** **Jon E. Clark, Ph.D.,** *Associate Director for Policy Development and GMP, Office of Pharmaceutical Science, Center for Drug Evaluation and Research,* **U.S. Food and Drug Administration** **Implementation of Quality by Design in Biotechnology Product Development: Industry Perspective** **Anthony R. Mire-Sluis, Ph.D.,** *Head of Product Quality and External Affairs,* **Amgen Inc.**			
5:45 pm - 7:15 pm	*Networking Cocktail Reception in Exhibit/Poster Hall Sponsored by* invitrogen™ *• Dedicated Poster Viewing*			

Wednesday, November 8, 2006 — *Exhibit Hall Hours: 9:45 am - 2:00 pm*

7:30 am - 8:00 am	*Coffee and Technology Workshop Sponsored by Invitrogen*			
	Production & Economics	**Scaling Up**	**Cell Culture and Upstream Processing**	**Recovery and Purification**
8:00 am – 12:00 pm	Audience Interactive Panel Discussion and Workshop: Quality by Design		Cell Line Engineering & Clone Selection	Technology Transfer of Downstream Processing Strategies for Process Validation and Characterization
12:00 pm - 12:30 pm	*Technology Workshops sponsored by GE Healthcare, SAFC and Stedim*			
12:30 pm - 2:00 pm	Luncheon in the Exhibit Hall and Final Opportunity for Poster and Exhibit Viewing			
2:00 pm - 6:00 pm	*Site Tour to Baxter BioScience* *(Open to first 50 registrants – see page 9 for details)*		Medium Choice & Development Process Characterization and the Process and Product Quality Relationship	Use of Disposables in Bioprocessing – Plastics & Elastomers Regulatory Guidance in Downstream Processing

Thursday, November 9, 2006 — *Exhibit Hall Closed*

	Cell Culture and Upstream Processing	Recovery and Purification
8:00 am - 11:45 am	Process Development & Optimization	Controlling Protein Structure Process Monitoring
11:45 am - 12:15 pm	*Technology Workshops sponsored by Bio-Rad Laboratories and Invitrogen*	
12:15 pm - 1:30 pm	Luncheon and Presentation Sponsored by PALL Life Sciences Filtration. Separation. Solution.	
	Cell Culture and Upstream Processing	**Recovery and Purification**
1:30 pm - 5:00 pm	Scale Up / Scale Down Case Studies Large Scale Process Troubleshooting	Recovery and Purification from High Titer Feedstocks

1 Production & Economics of Biopharmaceuticals

7:00 *Registration and Coffee*

Achieving Operational Efficiencies

8:00 **Chairperson's Remarks**

Peter F. Moesta, Ph.D., *Divisional Vice President, Biologics Manufacturing,* **Abbott Bioresearch Center**

8:15 **Featured Presentation**

Lean Manufacturing in a Biologics Environment

Operational Excellence has traditionally been applied to high volume, low profit margin manufacturing operations such as the automotive industry. Only during recent years have Biologics Manufacturers realized significant benefits from the successful utilization of such strategies. This presentation reviews the use of Lean Manufacturing in a large scale, recombinant protein biologic manufacturing environment and the results that have been achieved.

Graham Brearley, Ph.D., *Senior Director of Operations,* **Baxter Bioscience**

8:45 **A New Era in Biotechnology**

The biotechnology industry has produced a number of important products that have significantly improved patient health, but are expensive to develop and manufacture. As healthcare providers continue to reduce costs, growth of the industry depends upon bringing candidate products through clinical development rapidly and cost-efficiently. Additionally, overall manufacturing costs must be reduced for patient access to these important clinical products.

S. Robert Adamson, Ph.D., *Vice President, Process and Product Development,* **Wyeth BioPharma**

9:15 **Design of Quality Systems with a Perspective on Operational Efficiency**

The design of effective and compliant quality systems does not conflict with the establishment of processes that ensure optimal cycle times for testing and product release. This presentation will describe various approaches for examining potential improvements in elements for product evaluation and release, using process excellence tools, to optimize operational efficiency.

Juan Torres, Ph.D., *Director, Quality Operations,* **Biogen Idec, Inc.**

9:45 *Networking Refreshment Break*

10:15 **Applying LEAN Principles to Improve the Performance of Purification Operation at Genentech** — Case Study

Optimizing process performance is a priority for Product Operations at Genentech because it supports meeting increased patient demand for our medicines. Tanks used in manufacturing are steam sanitized between each use. Sanitization was identified as the key bottleneck of the purification process. Using the LEAN/DMAIC data driven approach, reduction in both the mean and the variations in tank sanitization time were achieved without engineering or automation changes leading to an increase in production volume.

Fadel Hamed, Ph.D., *Process Owner-Operational Excellence Training and Methodology,* **Genentech, Inc.**

10:45 **Lean Manufacturing Implementation at a Biotech API Plant**

Abbott Bioresearch Center set out to transform itself into a more competitive manufacturer of both internal and third party products through application of Lean Manufacturing principles. The ABC strategy built core teams to define and implement change, utilizing a lean consultant as a facilitator. This presentation will describe the real-world application of Lean to biomanufacturing.

Joshua Froimson, *Senior Manufacturing Manager,* **Abbott Bioresearch Center**

11:15 **Framework for Providing Effective Technical Support to a High Volume Manufacturing Operation for a Blockbuster Drug**

The presentation will describe a framework for manufacturing support, process performance monitoring and continuous improvement at one of Amgen's commercial manufacturing facilities. Examples of successes, pitfalls and opportunities will be provided. Resource requirements and infrastructure needs for an effective manufacturing support organization will be outlined. Aspects of attracting and retaining talent in a routine support environment will also be discussed.

Sourav Kundu, *Associate Director, Process Development,* **Amgen, Inc.**

2 Scaling Up from Bench through Commercialization

7:00 *Registration and Coffee*

Smart Process Engineering to Save Time, Money and Ensure Quality

8:00 **Chairperson's Remarks**

Rhona O'Leary, Ph.D., *Director, BioProcess Development,* **Genentech, Inc.**

8:15 **Large-Scale Pool-Less Purification: Applications towards Reducing Overhead Cost and Production Time**

As cell culture titers increase, the purification trains in existing manufacturing plants are becoming seriously undersized. Existing plants can expand their capacity by buying larger chromatography columns. However, the tank volumes required to run the columns may be space and cost prohibitive. We will describe the development of a clinical-scale "connected process" utilizing in-line dilution to reduce buffer volumes and eluting columns directly onto successive columns to eliminate pooling tanks.

Joseph E. Shultz, *Senior Scientist, Purification Process Development,* **Amgen Inc.**

8:45 **Rapid Development of a Therapeutic Moncolonal Antibody**

An accelerated, economical, low-risk development strategy is presented for staging specific activities while deferring resource-intensive activities until Phase I clinical trials. This strategy allowed us to move a product from benchtop to IND in 7 months and to conduct additional toxicology studies, develop a second-generation cell line, optimize the manufacturing process, and demonstrate product comparability while completing Phase I clinical trials.

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

9:15 **Benefits of Using a Purification Process Platform Felt across Functional Areas** — Case Study

We have recently completed production of an antibody for use in the clinic using Genentech's purification platform. Use of the platform allowed for concomitant purification process development of three molecule variants that aided final molecule selection and enabled modular viral validation. This approach allowed the project to adhere to schedule and ensured appropriate use of manufacturing and development resources.

Martha Lovato Tse, Ph.D., *Associate Scientist, Early Stage Purification,* **Genentech, Inc.**

9:45 *Networking Refreshment Break*

10:15 **Development of a Platform Strategy for Novel Recombinant Protein Purification** — Case Study

Human Genome Sciences Inc. (HGS) has utilized albumin-fusion technology as a novel method for increasing the circulating half-life of therapeutic proteins. Proteins of interest are genetically fused to human serum albumin (HSA). The fusion to serum albumin provides a common element around which to develop a process. We have implemented a platform strategy for production of HGS' HSA-fusion proteins.

Araba Lamousé-Smith, Ph.D., *Section Head, Purification Sciences,* **Human Genome Sciences, Inc.**

10:45 **Practical Application of Single Use Pod Filters in Downstream Filtration Operations**

With recent advances in disposable technology the use of depth filtration can be more readily implemented for use with problematic feed streams in downstream operations. Lonza Biologics, Inc. has implemented the use of Pod Filters (Millipore) for multiple processes to aid in harvest clarification as well as in downstream applications. The application of these filters will be discussed.

Keith Kellerman, *Process Development Scientist,* **Lonza Biologics Inc.**

11:15 **Evaluation of the Millipore Pod Technology at Various Scales: An End User's Perspective** — Critical Evaluation

The scale-up process of depth filtration remains a challenge. Operability of traditional lenticular devices can be problematic in terms of time and safety in large-scale manufacturing. Biogen Idec scale-up facility has evaluated a new alternative depth filtration approach by Millipore called the POD. The operability and scalability of this system was compared to traditional lenticular options. Additionally, membrane performance was assessed between Millipore and other filter vendors in the biotech industry for a mammalian cell culture process.

John Paul Smelko, *Engineer II, Technical Development – Pilot Plant,* **Biogen Idec, Inc.**

11:45 Concurrent Technology Workshops

A Comparison of Conventional and Controlled Freezing Methods

Technology Workshop sponsored by STEDIM BIOSYSTEMS

Conventional freezing at production scale present challenges to biologics due to macroscopic freeze concentration of solutes. This effect results in concentration changes occurring differentially throughout the frozen volume. Controlled freezing is presented as a method capable of minimizing this freeze concentration. The concentration distribution varies significantly depending upon the method and scale used. The presentation compares conventional and controlled methods.

Mathew Olsen, *Applications Scientist,* **Stedim Biosystems**

Single Use TFF – Justification, Operation & Performance

Technology Workshop sponsored by MILLIPORE

Single-use TFF is gaining popularity due to its ease-of-use and ability to reduce time-to-market & free-up precious resources. Additionally, an equally important benefit is risk mitigation. This presentation quantifies the economic benefits of single-use TFF including the associated risk mitigation, and then presents data comparing the hydraulic performance and scalability to traditional multi use TFF.

David B. Rubin, CAPM, *Product Manager, Mobius Solutions,* **Millipore Corporation**

1 Production & Economics of Biopharmaceuticals

Effects of Regulatory Requirements on Economics

1:45 **Chairperson's Remarks**

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

2:00 **Evolution of Science-Based Quality Systems and Incorporation of Risk Assessment**

The 21st century has seen rapid evolution of science-based quality systems, with initiatives from FDA and other regulatory agencies towards defined systems of quality management. Such initiatives have culminated in the development of new ICH draft guidelines Q8, 9 and 10 that incorporate expectations of the role of risk assessment in quality systems. This presentation summarizes the principal elements of a science-based quality system and outlines practical benefits and limits of approaches to risk assessment.

Alasdair Shepherd, Ph.D., *Director, International Quality,* **Biogen Idec BV,** *The Netherlands*

2:30 **Comparability for Post-Approval CMC Changes** Case Study

Genentech and its partners have demonstrated post-approval comparability for numerous manufacturing site transfers, process changes, and new formulations. Guidelines have been developed for quantitative and chromatographic data acceptance criteria. A decision tree for physicochemical, biological, non-clinical, and/or clinical assessments has also been developed. Comparability case studies will be presented, including examples where physicochemical analyses were supplemented with in-vivo studies.

Reed Harris, *Director, Late Stage Analytical Development,* **Genentech, Inc.**

3:00 **Comparability of a Combination Product during Scale-up and Process Improvements** Case Study

OP-1 Implant® stimulates healing of bone. It is manufactured by combining Osteogenic Protein 1 (BMP-7) and type I collagen, vacuum drying, then sterilizing by irradiation. A program to scale up the manufacturing process included changes to compounding, reduction of solvents, and a new container closure. Comparability of the scaled up to commercial product as assessed by release, characterization, and stability testing will be discussed.

Amy Dingley, Ph.D., *Director of Quality,* **Stryker Biotech**

2 Scaling Up from Bench through Commercialization

Comparability Strategies to Support Process Changes throughout Development

1:45 **Chairperson's Remarks**

Daotian Fu, Ph.D., *Senior Director of Bioanalytical Development,* **Genzyme Corporation**

2:00 **Challenges in Understanding Protein Aggregation during Bioprocess Development** Case Study

Protein aggregation during bioprocessing poses a challenge for drug storage, safety and efficacy. Case studies presented will highlight two aspects: impact of bioprocessing stresses on the pathway of antibody aggregation, and comparison of specific aggregation pathways of a PEGylated protein with respect to the original molecule. Such studies could potentially be relevant to efforts to compare follow-on's to the innovator product.

Rahul S. Rajan, Ph.D., *Senior Scientist,* **Amgen Inc.**

Featured Presentation

2:30 **A Proactive Approach to Developing Specifications for GARDASIL®, a New Vaccine against Human Papillomavirus** Case Study

A proactive approach was used for developing specifications for GARDASIL®, Merck's recombinant human papillomavirus virus-like particle vaccine. The proposed specifications were derived by evaluating process and analytical variability and a propagation-of-error model to estimate final container variability. Expiry limits were derived by modeling available stability data. To confirm that limits were appropriate, they were validated using a "potency-ranging" clinical study.

Robert Sitrin, Ph.D., *Executive Director, Bioprocess and Bioanalytical Research,* **Merck & Co., Inc.**

3:00 **Validating a New Plant for the Production of Xolair® Bulk Drug Substance** Case Study

The Xolair drug substance production process has been successfully transferred from a Genentech plant located in US, to a new Novartis plant located in Europe. The aim of this joint effort was validating the new plant and demonstrating product and process comparability. Focus: late equipment qualification phase, preparing and performing the qualification batches. Highlights: up and downstream studies, full scale engineering runs, cleaning validation, pre-approval inspection.

Leopold E. Bertea, Ph.D., *Head of Production,* **Novartis Pharma S.A.S.,** *France*

3:30 *Networking Refreshment Break*

Keynote Presentations

4:00 **Using Bioprocess Manufacturing as a Strategic Advantage**

Brett L. Schmidli, *President,* **Schmidli & Associates;**
former Senior Vice President, Technical Operations, **PDL BioPharma, Inc.**

Please see page three for complete abstract.

4:45 **Operational Excellence – Achieving World Class Performance**

Tim Moore, *Vice President of South San Francisco Manufacturing Operations,* **Genentech, Inc.**

Please see page three for complete abstract.

5:30 **Exhibit Hall Opens with Cocktail Reception** *Sponsored by* SAFC Biosciences™ Accelerate Success™

Network with your peers, learn about new products and services from over 80 exhibiting companies, and see cutting-edge data in a large group of posters.

1 Production & Economics of Biopharmaceuticals

7:00 *Registration and Coffee*

Facilities and Flexible Capacity Planning

8:00 **Chairperson's Remarks**

Frank Jackson, *Vice President,* **Genentech Vacaville Product Operations**

8:15 **Capacity Strategy for ORENCIA®** Case Study

With the launch of their first internally developed biologic, ORENCIA®, BMS has bridged their in-house biologic manufacturing capacity via strategic partnerships with CMOs. This strategy provides BMS with additional capacity while they build their own large-scale multi-product bulk manufacturing facility to meet market demands for ORENCIA and to provide long-term capacity for the Company's future biologics in their pipeline. BMS' strategy for securing incremental biologics manufacturing capacity will be discussed.

Cynthia K. Ulrich, R.Ph., M.Sc., *Director, In-licensing and Biologics Strategies, Technical Operations,* **Bristol-Myers Squibb**

8:45 **Process Modeling and Development: Identifying the Best Return for Investment**

Abstract unavailable at press date; please visit www.IBCLifeSciences/BPI/US for program updates.

Joost Quaadgras, *Associate Research Fellow, Global Biologics,* **Pfizer Inc**

9:15 **Capacity Planning: When Do You Know You Have Enough?**

Having sufficient capacity is critical in our industry, specifically when you are producing life-saving drugs.
How do you know when the capacity you have is enough? This talk will explore the factors that affect capacity planning and different ways to look at your capacity requirements to ensure you can meet market demand.

Susanne Somerville, *Director, Supply Chain Strategic Planning,* **Genentech, Inc.**

9:45 *Networking Refreshment Break in Exhibit and Poster Hall*

10:30 **Lowering Product Cost for Production of Monoclonal Antibodies via Process Innovation**

The presentation discusses process innovations aimed at improving the efficiency of manufacturing operations and facilities and reducing product cost per gram for monoclonal antibody production in mammalian cell culture. Implementation of the process into appropriately equipped facilities could dramatically reduce product cost per gram based on comparative cost of goods analysis.

K. Scott Camberg, M.S., *Bioprocess Associate III, Fermentation & Cell Culture Sciences,* **Human Genome Sciences, Inc.**

2 Scaling Up from Bench through Commercialization

7:00 *Registration and Coffee*

Regulatory Trends Impacting Biopharmaceutical Manufacturing and Scale Up

8:00 **Chairperson's Remarks**

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

Featured Presentation

8:15 **Complying with CGMPs For Investigational Clinical Studies**

FDA recently articulated an incremental approach for complying with CGMPS during investigational drug development. This presentation will explore this approach in greater detail including challenges for biotechnology products.

Christopher C. Joneckis, Ph.D., *Senior Advisor for CMC Issues, Office of the Director,* **CBER, US FDA**

8:45 **The New Requirement for Virus Safety Assessment of Clinical Trial Material in Europe**

Virus safety assessment is required early in product development. Besides demonstrating absence of infectious agents in the cell line, the capacity of the process to remove/inactivate viruses needs to be demonstrated. In addition to retrovirus, a non-enveloped virus, like parvovirus, should be used. Historical data might be used in virus safety assessment. The new requirements will be discussed.

Hannelore Willkommen, Ph.D., *CEO,* **RBS Consulting,** *Germany*

9:15 **Shortcomings Seen by FDA in Scaling Up in Recent Approvals and Applications**

Abstract unavailable at press date; please visit www.IBCLifeSciences/BPI/US for program updates.

Carolyn A. Renshaw, *Biologist, OCBQ, DMPQ,* **CBER, US FDA**

9:45 *Networking Refreshment Break in Exhibit and Poster Hall*

10:30 **Efficient Process Development Strategies Can Translate into Robust Large-Scale Manufacturing** Case Study

Utilisation of scale down process models, factorial experimental design and a holistic design space approach has facilitated the rapid re-development of approved manufacturing processes and the development of robust and defined process. The result is the development of a process knowledge base, facilitating a post approval PAT approach, reduced cost, batch deviations and processes that support product out licensing due diligence efforts.

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

4 Recovery & Purification

7:00 *Registration and Coffee*

Applying Novel Process Technologies

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

Peter Wojciechowski, *Director, Purification Technology, Global Biologics Supply Chain,* **Johnson and Johnson**

8:15 **The Use of Hydrophobic Interaction Chromatography (HIC) in Commercial**

HIC columns are used in most therapeutic protein purification processes developed by Genzyme. Approved products that utilize HIC column purification steps include Cerezyme®, Fabrazyme®, Thyrogen®, Myozyme® and ATryn® (co-developed by GTC Biotherapeutics and Genzyme). Examples of HIC process steps that are used for: the reduction of endogenous protein impurity, removing clipped forms of a protein from the mature form, a high yield capture step and virus removal are included with this presentation.

Joseph P. Kutzko, *Principal Scientist, Therapeutic Protein Development,* **Genzyme Corporation**

8:45 **Computational Fluid Dynamics (CFD) Modeling of Commercial-Scale Chromatography Columns**

CFD model was developed to simulate the flow and mass distribution in commercial-scale chromatography columns. The model can be a valuable tool to improve flow distribution during the design phase of large-scale columns. The modeling results were compared to profiles observed in dye testing studies.

Naveen Pathak, M.S., *Senior Engineer, Manufacturing Science & Technology,* **Amgen Inc.**

9:15 **Large Scale Industrial Scale Protein Isolation – Relevance to Production** Case Study

As an example of robust operation of large scale downstream processing operational data for a plant isolating up to 20,000 kg/annum of lactoferrin and Immunoglobulin G from bovine whey (250,000 L whey per day) will be presented. The process consists of three EBA columns (250L, 800L, 500L) containing high density tungsten carbide-based adsorbents and operating at linear flow rates up to 2000 cm/hour with working capacities as high as 60 g/L (transferrin) and 30g/L (IgG).

Rob Noel, Ph.D., *Business Development Manager,* **UpFront Chromatography A/S,** *Denmark*

9:45 *Poster/Exhibit Viewing and Refreshment Break*

1 Production & Economics of Biopharmaceuticals

11:00 **Genentech's Rituxan Manufacturing at Lonza Biologics - A Win-Win Business Partnership** Case Study

In this joint presentation we will discuss how a win-win business partnership was conceived, executed, and now maintained between Genentech and Lonza Biologics. From process transfer to routine manufacturing, the presentation will focus on what was done and what we continue to do to maintain a successful partnership while incorporating the business drivers for both Genentech and Lonza.

Daniel J Moskey, *Associate Director Bulk Contract Manufacturing, Manufacturing Collaborations,* **Genentech, Inc.**

Steve Bottomley, *Associate Director Product Management,* **Lonza Biologics, Inc.**

11:30 **Outsourcing for Biopharmaceuticals: Beyond the US and Western Europe**

GMP manufacturing capacity that meets international standards is currently available in Asia (in South Korea, Singapore, Japan, and India) and in Eastern Europe. Additional vendor capacity is under construction in Malaysia, China and elsewhere. Support for methods development, testing, expression development and process development is also available outside the U.S. and Western Europe. In this presentation we will review a few of the premier sites for contract manufacturing and development and showcase the types of opportunities and challenges involved when outsourcing beyond USWE.

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

2 Scaling Up from Bench through Commercialization

11:00 **Purification Process Re-Engineering while Ensuring Product Comparability** Case Study

The project described in this presentation aimed at eliminating all animal-derived raw materials from the production and purification processes for a marketed product. The comparability between the drug substances generated with the approved and the new processes was demonstrated. The presentation will illustrate the strategies adopted during the development, scale-up and validation of the new purification process.

Alain Bernard, Ph.D., *Director, Biotech Process Development,* **Serono Biotech Center,** *Switzerland*

11:30 **Panel Discussion**

Regulatory Trends Impacting Biopharmaceutical Manufacturing and Scale Up

Moderator:

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

Panelists:

Christopher C. Joneckis, Ph.D., *Senior Advisor for CMC Issues, Office of the Director,* **CBER, FDA**

Carolyn A. Renshaw, *Biologist, OCBQ, DMPQ,* **CBER, US FDA**

Hannelore Willkommen, Ph.D., CEO, RBS Consulting, *Germany*

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

Alain Bernard, Ph.D., *Director, Biotech Process Development,* **Serono Biotech Center,** *Switzerland*

4 Recovery & Purification

10:30 **Evaluation of Different Primary Recovery Methods for E. coli Derived Recombinant Human Growth Hormone and the Compatibility with Further Downstream Purification** Case Study

A case study comparing different primary recovery routes and the compatibility with the capture chromatography step. will be presented. The primary recovery routes studied are standard clarification by centrifugation and extraction in aqueous two-phase systems. The extraction system was composed of a random copolymer of ethylene-oxide and propylene-oxide in combination with a starch.

Josefine Persson, Ph.D., *Scientist, Early Stage Purification,* **Genentech, Inc.**

11:00 **Affinity Precipitation as an Efficient Capturing Stepy**

Precipitation is by tradition used successfully. However, the resolving power needs to be up-graded. Smart polymers with bound ligands constitute a tool to achieve this separation. The polymers are soluble when binding the target molecule and after a small change in an environmental factor (pH, ionic strength or temperature), quantitative precipitation polymer-target protein complex will take place. After harvest, the target molecule may be released while the polymer can be recycled.

Bo Mattiasson, Ph.D., *Professor, Department of Biotechnology,* **Lund University,** *Sweden*

11:30 **Using Crystallization in a Scaleable Protein Purification Process** Case Study

Crystallization is an extremely specific and powerful purification method, but it is generally limited to analytical or preparative scales due to difficulties with scale-up to commercial production levels. However, we currently have in development a protein with a very unique molecular structure that allows it to spontaneously crystallize in a variety of simple buffer systems. Details are presented on the practical development of the purification process including generating solubility curves, measuring crystallization kinetics, affecting crystal size distribution, improving crystal filtration and washing efficiency, and maximizing purity and yield.

Tim Matthews, *Senior Engineer, Process Development Engineering,* **Genentech, Inc.**

Poster Presentations

Submit your abstract online today at www.IBCLifeSciences.com/BPI/US

Deadline for inclusion in BioProcess International™ Show Preview: August 1, 2006 • Final Deadline: October 9, 2006.

Share your research by presenting a poster at this event. This is a great opportunity to discuss your findings and field questions from interested attendees.

- One poster award winner from each conference track will receive a $150 award and certificate
- Space is limited to 75 posters
- Accepted poster abstracts will be viewable online as of October 9, 2006
- Posters will be displayed by conference track
- 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: BioProcess™ INTERNATIONAL

Poster and Exhibit Viewing Hours

Monday, November 6, 2006 • 5:30 pm – 7:00 pm
Tuesday, November 7, 2006 • 9:45 am – 7:15 pm
Wednesday, November 8, 2006 • 9:45 am – 2:00 pm

Dedicated Poster Viewing

Tuesday, November 7, 2006 • 6:00 pm – 7:00 pm

Poster presenters are asked to be at their posters during this time.

Poster Award Presentation

Winners will be announced in the December issue of BioProcess International™. 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'hx 8'w.

12:00 Concurrent Technology Workshops

Advancing toward a Fully Disposable Process

Technology Workshop sponsored by sartorius

Sartorius has introduced a number of disposable bioprocess components and systems that significantly advance toward the goal of a fully disposable process. Disposable solutions are presented for each unit operation in a typical mAb process at various scales. An analysis of the scaling limitations of specific disposable technologies is presented.

Paul Priebe, *Head of Product Management - Process Filtration & Disposable Technology,* **Sartorius North America**

Rapid Four-Fold Increase in Antibody Production through Utilization of AMDS DOE-Based Media Optimization and Hydrolysate Supplementation

Technology Workshop sponsored by BD

In our Autonutrient™ Media Design Service (AMDS), DOE-based media and process development procedures were employed to achieve a greater than 4-fold increase in huIgG production from CHO cells in less than 18 months. This involved optimization of a chemically defined base, an animal free hydrolysate optimization, and feed media optimization to increase production from 343mg/L to greater than 1.5g/L.

James W. Brooks, Ph.D., *R&D Program Manager,* **BD Advanced BioProcessing**

Bio-Rad Technology Workshop

Technology Workshop sponsored by BIO-RAD

Abstract unavailable at press date; please visit www.IBCLifeSciences/BPI/US for program updates.

12:30 Networking Luncheon in Exhibit Hall

Continue learning about new products and services from over 80 industry suppliers, gain new data from posters, and make new contacts by participating in roundtable discussions organized by topic of interest.

Plenary Session — Tuesday Afternoon, November 7, 2006

Featured Case Studies in Successful Scale-Up and Cost Savings

2:00 **Chairperson's Remarks**

Ron Taticek, Ph.D., *Associate Director, Fermentation MSAT, SSF Biochemical Manufacturing,* **Genentech, Inc.**

Featured Presentations

2:15 **Xigris: From Process Development to Commercialization** — Case Study

Xigris (rhaPC) is a large glycosylated protein used for the treatment of severe sepsis. This presentation will review the process development and commercialization of Xigris. This will include: early and late phase process development, third party selection, technical transfer, scale-up and ongoing process oversight.

Andrew Cockshott, Ph.D., *Manager, Manufacturing Science and Technology,* **Eli Lilly and Co.**

2:45 **Strategies to Expedite Supply of Quality Monoclonal Antibody: A Case Study from Bench to Clinic** — Case Study

A case study is presented to demonstrate that flexible utilization of existing platforms and timely implementation of new technologies could lead to expeditious process development. Special emphasis is placed on how the team solved problems encountered during development and manufacturing and met an aggressive timeline. Strategies are also shown for the successful supply of quality monoclonal antibody for clinical use.

Shue-Yuan Wang, Ph.D., *Senior Group Leader, Process Sciences,* **Abbott Bioresearch Center**

3:15 **Synchronizing Process and Product Development Early Phases to Reduce Time to Clinic** — Case Study

This presentation will illustrate that efficient product development can only be achieved with an integrated strategy that properly anticipates process changes and synchronizes scale-up efforts with product development phases. The early development phases of a monoclonal antibody will be discussed as an example, including data from our lab-to-pilot scale technology platform.

Frederic Meuwly, Ph.D., *Senior Project Manager, Manufacturing Product Development,* **Serono International S.A.,** *Switzerland*

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

Keynote Presentations

4:15 **Improving FDA Regulation of Product Quality**

Jon E. Clark, Ph.D., *Associate Director for Policy Development, Office of Pharmaceutical Science, Center for Drug Evaluation a*

U.S. Food and Drug Administration

5:00 **Implementation of Quality by Design in Biotechnology Product Development: Industry Perspective**

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

Amgen Inc.

Please see page three for complete keynote abstracts.

5:45 **Networking Reception in Exhibit and Poster Hall**

Sponsored by invitrogen invitrogen™

Dedicated Poster Viewing 6:00-7:00 pm. Poster presenters are requested to be at their posters during this time frame to answer attendees' questions regarding their novel data.

7:30 *Coffee &* **Technology Workshop**

Sorting It All Out – From Gene to Stable Cell Line

Technology Workshop sponsored by invitrogen™

The process of creating a suitable mammalian cell expression system for protein production involves three critical steps: (1) Selection of host system, (2) Constructing a suitable vector, and (3) Stable clone creation / optimization. In this workshop, critical factors and enabling technologies involved in each step will be discussed.

Mugdha Gadgil, Ph.D., *Scientist, PD-Direct Services,* **Invitrogen Corp.**

1 Production & Economics of Biopharmaceuticals

2 Scaling Up from Bench through Commercialization

Audience Interactive Panel Discussion and Workshop

Quality by Design: Evaluating Practical Aspects and Implementation

In this interactive workshop session, discussion will pick up where the Tuesday evening keynote presentations ended. Topics include how industry can balance additional product and process characterization, design of experiments, PAT and other quality by design (QBD) tools without hampering development timelines.

Panelists will offer their insights on these challenging questions:

- Can QBD reduce process validation requirements?
- What regulatory relief can QBD provide for post-approval changes?
- Putting QBD into marketing applications: where and how much?
- How can one assess the value of in-depth process characterization versus the potential for timeline delays?
- Where should QBD start -- in discovery, research or development?
- How can industry apply risk management techniques to QBD in order to achieve highest value outcomes?
- Bring your own questions and comments and contribute to this interactive session, to advance your knowledge of this new frontier of biopharmaceutical production.

Co-Moderators:

Jon E. Clark, Ph.D., *Associate Director for Policy Development and GMP, Office of Pharmaceutical Science, Center for Drug Evaluation and Research,* **U.S. Food and Drug Administration**

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

Panelists:

Barry Cherney, Ph.D., *Deputy Director, Division of Therapeutic Proteins, Office of Biotechnology Products, OPS, CDER,* **U.S. Food and Drug Administration**

Alasdair Shepherd, Ph.D., *Director, International Quality Group,* **Biogen Idec BV,** *The Netherlands*

Tobias Massa, Ph.D., *Vice President, Global Regulatory Sciences – CMC,* **Bristol-Myers Squibb**

Wassim Nashabeh, Ph.D., *Director, CMC Regulatory Affairs,* **Genentech, Inc.**

Schedule:

8:00 *Co-Moderators' Opening Remarks and Panel Introductions*
8:15 *Discussion Begins*
9:45 *Poster/Exhibit Viewing and Refreshment Break*
10:30 *Discussion Resumes*
11:45 *Discussion Ends*

3 Cell Culture & Upstream Processing

Cell Line Engineering & Clone Selection

8:00 **Chairperson's Opening Remarks**
Timothy S. Charlebois, Ph.D., *Director, Cell & Molecular Sciences,* **Wyeth BioPharma**

8:15 **Genomic Analysis and Engineering of Cell Lines for the Production of Recombinant Proteins**
Due to its large size and complexity, the expression level of rFVIII in mammalian cells is 2-3 orders of magnitude lower than other recombinant proteins. In comparison with other cell lines, such as CHO, HEK293 and BHK-21, HKB11 cells express 10- fold higher levels of FVIII. To identify factors that promote FVIII expression, we have used flow cytometry, protein analysis and cDNA microarrays to compare cell clones expressing different levels of rFVIII. The applications of these studies to cell line engineering will be presented.
John E. Murphy, Ph.D., *Manager, Expression Technologies,* **Bayer HealthCare**

8:45 **Trying to Consistently Find the Sweet Spot for Antibody Expression**
We are working to combine two technologies, a high-throughput secreted molecule quantitation assay and a site-specific recombination system, to allow a process of continuous cell line development. The goal of this strategy is to continuously improve a current production cell line to possess new and desirable traits, while allowing for a precise exchange of antibody expression units at any point in the future.
Bob DuBridge, Ph.D., *Senior Director, New Technologies,* **PDL Biopharma**

9:15 **Genetic, Epigenetic and Phenotypic Variation in Cell Populations during Development** Case Study
Cell line stability is considered an important attribute of mammalian cell clones chosen for large-scale production. A case study of a recombinant mAb cell line will be presented that exhibited instability during development. Detailed analysis revealed striking conclusions regarding cell heterogeneity as well as genetic and epigenetic events that occurred during development.
Timothy S. Charlebois, Ph.D., *Director, Cell & Molecular Sciences,* **Wyeth BioPharma**

9:45 *Poster/Exhibit Viewing and Refreshment Break*

4 Recovery & Purification

Technology Transfer of Downstream Processing

8:00 **Chairperson's Opening Remarks**
Scott Borneman, Ph.D.

8:15 **Technology Transfer Considerationsfor the Relocation of a Commercial Manufacturing Process to a Different Facility** Critical Evaluation
The relocation of a manufacturing process from one facility to another requires a number of decisions during the technology transfer process. As one example, a commercial manufacturing process was transferred from one licensed facility to another facility. The existing process used a depth filter as a harvest method; the intended manufacturing area was designed for a microfiltration. A comparative evaluation of the risks and benefits of the two technologies was performed.
William K. Wang, Ph.D., *Senior Manager, Manufacturing Sciences,* **Biogen Idec**

8:45 **Transferring a Monoclonal Antibody Process: Strategies for Successful Technology Transfer** Case Study
A critical requirement to ensuring the successful execution of a technology transfer project is an understanding of, and the ability to plan for, the needs, challenges, and risks associated with each phase of the transfer process. This presentation will use the recent transfer of a manufacturing process for a therapeutic monoclonal antibody to provide a case study on how to address and manage these concerns to deliver a successful technology transfer.
David Peers, *Senior Manufacturing Technology Specialist, Bioprocess Development, Late Stage Purification,* **Genentech, Inc.**

9:15 **Achieving Successful Biotech Process Technology Transfer to a New Start-Up Site**
Transfer of manufacturing processes for biopharmaceuticals between sites can present significant technical challenges as well as opportunities; particularly when it is to a completely new start-up facility. This presentation reviews the approach taken to transfer a licensed biopharmaceutical from an established site in the USA to Ireland. The speaker will discuss their experience of negotiating the technology transfer process and the route taken to achieve a successful outcome.
Martin Addo, Ph.D., *Associate Director, Drug Substance Manufacturing Technology,* **Wyeth,** *Ireland*

9:45 *Poster/Exhibit Viewing and Refreshment Break*

3 Cell Culture & Upstream Processing

10:30 **Cell Banking and Seed Train: Process Improvements for Increased Process Robustness**

Variable performance at thaw or in the seed train can impact the robustness of your cell culture process. This presentation describes development and implementation of two process improvements, the seed train bioreactor and large volume ampule working cells banks, that eliminate the labor-intensive and often variable expansion of cells in large volume spinner flasks without pH and dissolved oxygen control.

Ron Taticek, Ph.D., *Associate Director, Fermentation MSAT, SSF Biochemical Manufacturing,* **Genentech, Inc.**

11:00 **High-Throughput Product Quantity and Quality Assays for Cell Line and Cell Culture Development** Case Study

To address the quantitative and qualitative aspects associated with cell line and cell culture process development, we have developed and implemented high-throughput screening systems to monitor protein quantity and functional activity. Additionally we have developed a high-throughput purification system and high-throughput analytical assays to assess protein quality. These systems enabled screening of a large number of clones and culture conditions within a shortened time frame.

Judy H. Chou, Ph.D., *Principal Research Scientist/Group Leader, Analytical Development and Support Group, Drug Substance Development,* **Wyeth Biotech**

11:30 **Integrating FACS-Based Subcloning into Cell Line Development: Steps towards Higher Efficiency and Production** Case Study

Fluorescence-activated cell sorter (FACS) based sorting methods provide an opportunity to methodically increase cloning efficiency and overall titer. However, separating high producing starting populations is relatively difficult, due to the quick saturation of current secretion assays. We have developed a 2-color Fluorescence-activated cell sorter (FACS) sorting approach based on dihydrofolate reductase (DHFR) expression and secreted product capture. Two assays were developed using either gel-microdrop encapsulation or surface affinity capture to measure single cell secretion rates. Altogether, we found our gel encapsulation based approach to be superior. The assay has been optimized for use in exceptionally high producing CHO populations, is significantly shorter, and can be adapted to different molecules.

Rohini Deshpande, Ph.D., *Principal Scientist, Protein Science,* **Amgen Inc.**

4 Recovery & Purification

Strategies for Process Validation and Characterization

10:30 **Characterization of an Ion-Exchange Chromatography Step of a Recombinant Protein Purification Process** Case Study

This case study outlines a characterization strategy for classifying operational and performance parameters and setting operating ranges and acceptance criteria as a prelude to validation of an ion-exchange chromatography unit operation. Methods for incorporating results of risk analysis; scale-down model qualification; and impurity clearance, robustness, edge-of-range, and worst-case studies into a coherent picture of the step's design space are discussed.

Steven K. Rausch, Ph.D., *Senior Scientist, Purification Process Development,* **Amgen, Inc.**

11:00 **Revisiting and Updating a Process Validation Package** Case Study

The validation status of an existing commercial manufacturing process using critical quality attributes (CQAs) and critical process parameters (CPPs) was assessed as the basis for establishing a defendable rationale. This presentation will highlight the challenges encountered during identification of CQAs, and CPPs and the development of a consensus regarding the process validation strategy.

Li-Chung Huang, MBA, MS, PE, *Senior Process Scientist, Global Technical Services, Global Biological Supply Chain,* **Johnson and Johnson**

11:30 **Modular Viral Validation**

Modular viral validation was first introduced in the "FDA Points to Consider in the manufacture and testing of monoclonal antibody products for human use" (1997). At Genentech, we have set strict requirements for application of modular viral validation for molecules in clinical development. Stringent definitions and requirements for application of modular viral validation will be addressed. Examples of how to apply modular viral validation to an antibody recovery process, using inactivation, filtration, and chromatography unit operations, will be presented.

Sherrie Curtis, *Senior Research Associate, Late Stage Purification,* **Genentech, Inc.**

12:00 Concurrent Technology Workshops

Vaccine Manufacturing Approaches

GE Healthcare

Technology Workshop sponsored by

Over the last years there has been a growing interest in large entities like viruses and drug delivery systems such as liposomes and micelles for transporting complex biomolecules as new therapeutic agents. This has created a need for fast, simple, safe and inexpensive manufacturing scenarios which emphasize maximal productivity and robustness with good process economics. Here, we will focus on the different generic principles that can be used when developing purification processes for such large entities based on ultrafiltration and chromatography.

Guenter Jagschies, Ph.D., *Director of Applications Research, R&D,*
GE Healthcare, *Sweden*

Single Cell Isolation of High-Producing Mammalian Cell Lines from a Transfectant Pool or Clonal Population

Technology Workshop sponsored by

SAFC Biosciences™ | Accelerate Success™

The Cell Xpress™ service, marketed by SAFC Biosciences, is a time- and labor-saving alternative to traditional clone selection approaches. The service uses the LEAP (Laser-Enabled Analysis and Processing) system to combine in situ imaging with laser manipulation to identify, purify and monitor expansion of high secreting clones. The workshop will focus on using LEAP to isolate productive clones from a transfectant pool or clonal population.

Kevin Kayser, Ph.D., *Manager, Research and Development, Cell Line Engineering and Development,* **SAFC Biosciences**

Mark Gerber, Ph.D., *Senior Scientist, Research and Development and Team Leader, LEAP System Customer Projects,* **SAFC Biosciences**

Beyond Leachables and Extractables, Validation of Single-use Bioprocessing Systems

Technology Workshop sponsored by

STEDIM BIOSYSTEMS

A comprehensive validation strategy is critical to successful implementation of single-use bioprocessing systems. This seminar will explore important aspects of validating single-use bioprocess systems, including: protein adsorption, microbial ingress, and specific risk-based validation studies. Validation services provided by Stedim Biosystems will also be reviewed.

Andrew Sette, *Corporate Director of Quality and Regulatory Affairs,* **Stedim Biosystems**

12:30 *Lunch and Final Poster and Exhibit Viewing Opportunity*
2:00 *Optional Site Tour to Baxter BioScience's Hayward Facility*

3 Cell Culture & Upstream Processing

Medium Choice & Development

2:00 **Chairperson's Remarks and Overview – Approaches to Medium Development and Optimization**

Several time-tested approaches are widely used in industrial medium development and optimization projects. In addition to these gold standards, newer systems biological approaches utilizing genomic, proteomic and metabolomic data are being employed. Furthermore, novel high-throughput culture model systems are being developed. The complimentarity of the standard approaches coupled with the high-throughput models and the systems approaches will be discussed.

Laurie Donahue-Hjelle, Ph.D., *Technical Manager,* **SAFC Biosciences**

2:30 **Replacement of Animal-Origin Raw Materials in Cell Culture Media – Current State-of-the-Art and Historical Perspective** Case Study

Regulatory agency guidance on raw materials used in the production of human biotherapeutics has prompted an evolving definition of what constitutes an animal-derived component. This presentation will trace the shift from "animal-origin" to "animal-origin-free" raw materials and discuss recent developments in sourcing of non-animal replacements. Benefits as well as potential problems associated with non-animal derived components will be discussed.

Stephen Gorfien, Ph.D., *Director, Customer Applications, BioProduction Systems and Services,* **Invitrogen Corp.**

3:00 **Rational Approach to Media Development** Case Study

Historically, media development for mammalian cell culture has been performed in a non-rational way (often referred as "kitchen-sink approach"). Media are rarely developed by evaluating cellular activities and nutrient demands of cells in the bioreactor environment. A multi-disciplinary approach to rational media development for mammalian cell culture with a specific case study will be presented. The dynamic relationships of cell lines, metabolism, media, and process parameters will be discussed.

Shun Luo, Ph.D., *Scientist/Media Group Leader, Late Stage Cell Culture,* **Genentech, Inc.**

3:30 **Defined Medium Development for High Yielding Mammalian Cell Culture Processes** Case Study

A well-balanced medium and feed strategy has been developed for high productivity processes. This medium contains no serum or hydrolysate and can maintain high viability and high productivity for an extended period of time. Protein quality is not adversely affected.

Yen-Tung Luan, M.S., *Principal Engineer II,* **Wyeth BioPharma**

4:00 *Networking and Refreshment Break*

Process Characterization and the Process and Product Quality Relationship

4:30 **Current Methods for Determining Glycosylation**

Glycomics is a term used to describe the study of the pool of carbohydrate variants produced by the cell. In terms of a single glycoprotein, this translates to a pool of glycoforms that has a consistent protein structure but variable glycan structures. Progress in this area has been slow because of the difficulties of analysis of the inherent complexity and variety of carbohydrate structures. Current techniques for analyzing these structures will be evaluated and discussed.

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

4 Recovery & Purification

Use of Disposables in Bioprocessing – Plastics & Elastomers

2:00 **Chairperson's Remarks & Overview - Economic Process Models for the Use of Disposable Technology in Polishing**

Validated clearance of viruses and process derived contaminants is vital for the manufacturing of biopharmaceuticals under cGMP. The most powerful methods for the selective removal of impurities like DNA, host cell proteins, endotoxins and viruses are chromatography steps such as affinity and ion exchange during the capturing and polishing phase in downstream processing. Flow-through chromatography with anion exchange media is widely used for final purification of monoclonal antibodies and recombinant proteins with non-acidic IEP. A detailed cost model was developed to evaluate the use of a two-step chromatography strategy followed by an orthogonal virus and contaminant clearance platform and applied to industry case-studies. Significant overall savings were found and will be outlined for the different cost categories.

Uwe Gottschalk, Ph.D., *Vice President, Purification Technology,* **Sartorius,** *Germany*

2:30 **Process Economy of Production for Small Companies**

... typically means: early stage processes and material supply for pre-clinical/clinical development, in conjunction with limited experience and resources, as well as dependence on extensive outsourcing of process development and/or supply of GMP material. Control of timelines and overall expenses are of outmost concern. Access to the right technology, capacity, as well as know-how matching early stage requirements are key features. Obviously compromises have to be made in consideration of individual preferences and risk assessment, especially in regard to the interpretation of regulatory guidelines for early development.

Frank Hanakam, Ph.D., MBA, *Vice President, Process Development,* **Micromet AG,** *Germany*

3:00 **Use of Disposable Technology for Very Large-Scale Chromatographic Purification**

Two challenges facing the bioprocess industry are practical application of disposables in downstream purification and handling the very large batches generated by process bioreactors with high expression levels. This talk describes a new system which combines disposable bioprocess column cartridges and disposable integrated valve Conferences to form multi-column, cycling systems able to process very large volumes with high economic efficiency.

Scott Fulton, M.S., *Chief Executive Officer,* **BioSystem Development, LLC**

3:30 **Assessing Leachables for Disposable Materials – A Risk Assessment Approach**

Once a decision is made to convert to disposable materials, it is important to be able to justify the change in terms of product impact and patient safety. This presentation describes some methodologies to evaluate what those risks might be, how to rank the risks, how to mitigate the risks, and how to document the decisions made. A thorough risk assessment can also define critical parameters and guide validation.

Robert Seely, Ph.D., *Process Biochemist,* **RMC Pharmaceutical Solutions**

4:00 *Networking Refreshment Break*

Regulatory Guidance in Downstream Processing

4:30 **PAT – Design Space for Biotech Products – How is it Defined?**

FDA has been asking industry to better understand and control it's processes since 1977; it has not wavered in it's position that firms must have 1) a detailed understanding of their manufacturing processes including the parameters necessary to control the process 2) defined the critical process parameters that are responsible for process variability that impacts product quality and 3) set up an appropriate monitoring and control system to ensure a robust process and consistent, compliant product. FDA has described PAT as a structure for describing the process, assessing variability, identifying critical process parameters and setting up the system to maintain the process in a state of control (Design Space). When appropriate, process and analytical technology innovations for production and data collection can then be applied to this system in the spirit in which FDA intended.

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

3 Cell Culture & Upstream Processing

5:00 **Harnessing Best Practice and Characterization for Fast Track Implementation and Validation of a Cell Culture Harvest Process**

The use of centrifugation and filtration is increasingly used for cell culture harvest at commercial scale. However, challenges remain for predicting performance from lab or pilot scale. This presentation will describe harnessing best practice and rigorous process characterization in order to scale, operate and validate a robust and efficient harvest process. Specific examples will be discussed.

Kenneth Green, Ph.D., *Principal Scientist,* **Amgen Inc.**

5:30 **Process Development and Comparability for Recombinant Human Bone Morphogenetic Protein-2** Case Study

A case study will be presented for development of the BMP-2 morphogenetic protein, wherein a comparability approach was taken to allow changes in cell culture, a more flexible downstream process design, and final transfer of the process to the commercial facility.

Jeffrey S. Deetz, Ph.D., *Senior Director, Drug Substance Development,* **Wyeth BioPharma**

6:00 *Close of Day 3*

4 Recovery & Purification

5:00 **Update on PDA's Biotech Advisory Board Projects, including Virus Filtration, Virus Spike Standardization, Reprocessing, Mycoplasma, Process Validation, and Updates of Existing Technical Reports**

Completed and on-going PDA projects related to biotechnology will be discussed. Several projects are related to viral clearance issues, including standard spike preparations, nomenclature systems, and viral safety during clinical trial manufacturing. Older Technical Reports are undergoing revisions, and current issues such as mycoplasma, in-vitro pyrogen assays, and reprocessing are also being addressed.

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

5:30 **Adventitious Agent Risk Assessment and Mitigation for E.coli and CHO Products** Case Study

In this presentation we describe a risk assessment for both E.coli and CHO derived products, including the likelihood, the consequences, and the impact of a contamination and methods for the mitigation and elimination of these potential risks. Response plans for the control of rodent parvovirus contamination and trending of environmental monitoring data are also included as part of our product protection strategies. Case histories for two past mammalian virus contaminations in large-scale fermentors and a more current mammalian virus contamination in a testing lab will be discussed. In addition, a mycoplasma contamination of plant peptones used in support of media fills will also be presented.

Barbara J. Potts, Ph.D., *Director, Quality Control and Virology,* **Genentech, Inc.**

6:00 *Close of Day 3*

Thursday Morning, November 9, 2006

3 Cell Culture & Upstream Processing

Process Development & Optimization

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

Charles Sardonini, Ph.D., *Research Scientist, Manufacturing Sciences and Technology,* **Amgen Inc.**

8:15 **Approaches to Achieving 5g/L through Process Development**

As biologics advance through the development pipeline, Phase II clinical data often indicate the need for higher therapeutic doses than suggested by pre-clinical studies. Cell culture process development offers the most straightforward approach to meeting clinical and commercial demands. This presentation will describe proven strategies for achieving cell culture titers of 5 g/L and higher, and also discuss the manufacturing and regulatory challenges that arise as a result of higher bioreactor productivities

Brian Turner, BioProcess Technology Consultants

8:45 **Rituximab Post-Approval Process Improvements and Process Transfers**

Rituximab (Rituxan®) is a chimeric monoclonal antibody originally approved in the US for the treatment of Non-Hodgkins lymphoma in 1997. Market demand for the product has grown rapidly in the U.S. and the rest of the world since its approval, with 2005 U.S. sales exceeding $1.8B. The continued success of this product has triggered an ongoing need for expanded manufacturing capacity. This has been accomplished through a combination of process improvements and process transfers to additional manufacturing facilities. This presentation will review the evolution of the rituximab manufacturing process through these improvements and transfers, including lessons learned.

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

4 Recovery & Purification

Controlling Protein Structure

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

David W. Kahn, Ph.D., *Director, Late-Stage Purification Development,* **Human Genome Sciences, Inc.**

8:15 **Improved Yields using High Hydrostatic Pressures to Disaggregate and Refold Biopharmaceutical Proteins**

Protein aggregates reduce yields and increase costs at multiple stages of manufacturing. High Pressure Disaggregation and Refolding of therapeutic proteins is a novel and effective alternative to traditional methods of removing protein aggregates and increasing yield of correctly folded protein. The theory of high pressure refolding, specific examples and scale-up options for manufacturing using high pressure technology will be presented.

Christian B. Allan, *Director of Research and Development,* **BaroFold, Inc.**

8:45 **In-Vitro GlycoPEGylation™ in Recombinant Therapeutic Manufacturing Processes** Case Study

Neose Technologies has developed processes that employ soluble glycosyltransferases to, (i) add and/or remodel glycan chains on glycoprotein drugs, and (ii) selectively add PEG to glycan chains. We will describe scalable unit operations that enable efficient manufacturing processes for GlycoPEGylation™ of therapeutic proteins expressed in various systems.

W. Scott Willett, Ph.D., *Senior Director, Process Development,* **Neose Technologies, Inc.**

3 Cell Culture & Upstream Processing

9:15 **The Optimization of Cell Lines and Culture Conditions for Increased Productivity of Recombinant Antibodies**

Rapid progress has been made in the optimisation of processes for producing recombinant antibodies from mammalian cells. Titers in excess of 1g/l are routinely obtained and this presentation will look at those aspects of cell line behavior and process performance that have contributed to high productivity. The talk will also address approaches that are likely to lead to further improvements in the future.

John Birch, Ph.D., *Chief Scientific Officer,* **Lonza Biopharmaceuticals,** *United Kingdom*

9:45 *Networking Refreshment Break*

10:15 **Comparison of Fluid Flow Profiles in 1-Liter and 15,000-Liter Bioreactors using Computational Fluid Dynamics**

Scale-down models are an essential tool for process development, process characterization, and commercial support. In this study, fluid flow profiles in the 1-liter benchtop bioreactor and the 15,000-liter production bioreactor were simulated using Computational Fluid Dynamics. Modeling simulations allowed a direct comparison of fluid flow profiles, shear rate distributions and turbulence characteristics in both systems.

Charles Sardonini, Ph.D., *Research Scientist, Manufacturing Sciences and Technology,* **Amgen Inc.**

10:45 **Innovative Solutions for the Production of New Viral Vaccines** Case Study

For the manufacture of viral vaccines, engineered cell lines and disposable production systems offer clear advantages over traditional approaches. The Per.C6™ cell line produces high titers of adenovirus compared to 293 cells. Maximum cell and virus production in Wave™ bioreactors reached at least those observed in stirred tank bioreactors. The production of influenza virus will also be discussed.

Florence Wu, Ph.D., *Director, Process Development for PD-Direct,* **Invitrogen Corporation**

11:15 **Appraising the SimCell for Process Development: From Start to Clinic**

The SimCell high throughput system is being evaluated for use in upstream development activities for mammalian processes. These activities include clone selection, process optimization, and process characterization. SimCell performance will be compared against performance in traditional vessels such as shakers and small bioreactors, as well as bioreactors used for clinical production.

Peter Harms, Ph.D., *Scientist, Cell Sciences & Technology,* **Amgen Inc.**

(*This presentation will be preceeded by a 5 minute introduction on* **High Throughput Microbioreactor Systems for the Development and Optimization of Biopharmaceutical Production Processes** by **James Hope,** *Vice President, Biotechnology,* **BioProcessors Corporation**)

4 Recovery & Purification

9:15 **Development of Downstream Process for an Antibody Containing Unpaired Cysteine Residue in Its Fab Domain** Case Study

We have observed significant variations in cell-based bioassay activity of an antibody. It was noted that the molecule contained unpaired cysteine residues in its Fab domains and that the free thiols were cysteinylated to different degrees. Treatment of the molecule with redox pair significantly improved its activity and molecular homogeneity and reduced the variations in its biochemical characteristics.

Yuefeng Lu, Ph.D., *Principal Scientist, Purification Process Development,* **Amgen Inc.**

9:45 *Networking Refreshment Break*

Process Monitoring

10:15 **Utilizing Analytical Tools to Guide Purification Development of a Protein Susceptible to Chemical and Proteolytic Degradation**

A Lilly therapeutic protein under development was susceptible to both proteolytic and chemical degradation. A strategy was developed that leveraged various analytical, purification, and characterization techniques, including the use of analytical reversed phase chromatography. The result was an increase in understanding of the molecule, which significantly influenced both upstream and downstream processing.

Peter K. Lambooy, Ph.D., *Senior Research Advisor, BioProcess Purification Development,* **Eli Lilly & Company**

10:45 **A Combined Proteomics and Combinatorial Approach to Utilizing Impurity Profiles to Direct Process Development for Complex Biological Products**

Various proteomic related methods (2D-Gel, LC/MS/MS, orthogonal potency- and immuno- assays) were used to track the flow of hundreds of proteins and fragments through a cascade of affinity adsorbents (Plasma Protein Purification System) designed to specifically capture six commercially important blood plasma proteins. The analytical use of combinatorial peptide libraries was employed to control the dynamic concentration range of the various complex protein mixtures generated for broad protein identification. Critical process parameters were identified to divert the flow of potent and safety-linked impurities away from select products.

Timothy K. Hayes, Ph.D., *Director of Analytical Chemistry, Plasma Derivatives Department,* **American Red Cross**

11:15 **Recirculated Size Exclusion Chromatography**

A new separation protocol using recirculated SEC and a sophisticated valve switching & peak fractionation procedure was developed and implemented successfully at production scale. After consecutive runs on the same column undesired product-related LMW species and/or impurities were reduced to undetectable levels. By using the SEC-loop protocol, the buffer consumption was reduced significantly and only one column instead of multiple stacked columns is required. An optimal column packing, a low linear flow rate and a low dead volume setup of the chromatography skid turned out to be critical for a good resolution. Results discussed include the influence of different process control parameters like use of alternative SEC resins, different column packing procedures, finetuning of peak cuts, impact of cycle number and different loading amount are discussed.

Norbert Palma, Ph.D., *Head, Downstream Pilot Plant, Biopharmaceutical Operations,* **Sandoz GmbH,** *Austria*

11:45 Concurrent Technology Workshops

Open Panel Discussion with Industry Experts – Process Optimization Using the Simcell™ System

Technology Workshop sponsored by invitrogen™

Automated, high throughput systems for bioprocessing have become a focal point for improving efficiencies in process development. Through microbioreactor design and integrated microfluidics, the SimCell™ system has emerged as a leading technology for process miniaturization. In this panel discussion, industry leaders will discuss the benefits and technical challenges related to the use of scale-down technologies for cell culture process development.

James Hope, Ph.D., *Vice President Biotechnology,* **BioProcessors Corporation**

Rational Design of IS CHO Feed: An Off-the-Shelf Solution for Improved Fed-Batch Culture Performance

Technology Workshop sponsored by IrvineScientific® Grow With Us

IS CHO Feed Medium was designed to provide improved growth and production from recombinant CHO lines in fed-batch culture. This medium was developed using spent media analysis from cultures of many cell lines then further optimized using three model cell lines. This medium provides good fed-batch culture performance that can easily be further optimized for specific cell lines and processes.

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

12:15 *Lunch and* **Technology Workshop**

New Sorbents for Mixed-Mode, Hydrophobic Interaction Chromatography

Technology Workshop sponsored by PALL Life Sciences — Filtration. Separation. Solution.℠

Although hydrophobic interaction chromatography (HIC) is an established production method for large-scale protein purification, the need to add lyotropic salts during binding and elution makes it both costly and environmentally challenging. A unique new mixed-mode chromatography method, which combines hydrophobic and ionic components gives process chromatographers versatility in protein purification, while also significantly reducing costs and environmental burdens.

Warren Schwartz, Ph.D., *Senior Technical Director, Chromatography Products,* **Pall Life Sciences**

3 Cell Culture & Upstream Processing

Scale Up / Scale Down Case Studies

1:30 **Chairperson's Remarks**

Janani Swami, Ph.D., *Associate Director, Cell Culture Operations, Allston Landing,* **Genzyme**

1:45 **Successful Scale-Up of the Synagis EYP Cell Culture Process to 12K: A Case Study** — Case Study

Synagis, MedImmune's first commercial monoclonal antibody, is produced in NS0 cells by the Enhanced Yield Process (EYP) at the 2,500 L scale in Frederick, MD. In 2003, the EYP was transferred/scaled-up to 12,500 L scale at our contract manufacturer Boehringer-Ingelheim (BI) in Germany. In 2005, the FDA granted MedImmune approval to implement the EYP for commercial manufacture of Synagis at BI. This presentation will describe the key challenges faced during process transfer/scale-up and will present select data pertaining to the following areas: (1) assessment of cell culture process performance (12K vs. 2K scales); (2) comparability of product quality (focus: Native IEF patterns and Oligosaccharide profiles); and (3) characterization of post-production NS0 cells (focus: co-cultivation).

David Lindsay, *Associate Director, Process Cell Culture,* **MedImmune, Inc.**

2:15 **Increasing Process Understanding for Legacy Cell Culture Products** — Case Study

Cell culture processes which were developed ten or more years ago present many challenges due to routine manufacturing practices which are constantly improving and changing to accommodate current cell culture processes. A case study will be presented summarizing the challenges of defining the critical process parameters and dealing with the evolution of a legacy cell culture process.

Tina M. Larson, Ph.D., *Senior Engineer, Fermentation Manufacturing Science and Technology,* **Genentech, Inc.**

2:45 **Scale Down Models – How Small Can You Go?**

There is a lot of interest in high throughput cell culture, which can most easily be achieved by a reduction in scale. This talk will focus on the challenges we face as we try to use smaller scale-higher throughput cell culture systems. What should be possible now? What problems will we face as we push the limits of small scale?

Craig Zupke, Ph.D., *Principal Scientist, Cell Sciences and Technology,* **Amgen Inc.**

3:15 *Networking Refreshment Break*

Large Scale Process Troubleshooting

3:30 **Design Requirements and Engineering Challenges for Large-Scale Stirred-Tank Disposable Bioreactors**

Although there are clear advantages for a single use disposable bioreactor, a lot of challenges exist for the design, operation, implementation, scalability, and comparability of such systems. In this work we present these issues and possible solutions for the development and implementation of a large-scale (1000L working volume) stirred tank bioreactor.

Sadettin S. Ozturk, Ph.D., *Director,* **Centocor, Inc.**

4 Recovery & Purification

Recovery and Purification from High Titer Feedstacks

1:30 **Chairperson's Remarks**

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

1:45 **Innocent until Proven Guilty? Scale-Dependent Impact of Cell Culture on Recovery Performance** — Case Study

The importance of recovery operations for linking cell culture and purification has prompted the development of reliable scale-down mimics. We report on the use of these mimics to investigate how attributes of cell culture and recovery conditions affect the removal or release of contaminants (e.g. particulates, host cell protein, DNA) during harvest. Understanding these process interactions helps process development to focus efforts on the factors that primarily determine harvest performance. The same scale-down mimics also prove useful for examining the causes of recovery performance changes during process scale-up or transfer. We will discuss results of equipment characterization test that help us to understand how harvest performance responds to changes in equipment and scale. The paper concludes by examining the implications of these results for the ability of current harvest technology to realize the productivity benefits of increasingly high density cell culture.

Lars Pampel, Ph.D., *Senior Scientist, Purification Process Development,* **Amgen Inc.**

2:15 **Integrating High Titer Cell Culture Processes with Highly Efficient Purification Processes for the Manufacturing of Human Monoclonal Antibodies**

Extensive upstream process development of CHO production systems for Hu Mabs resulted in high specific productivities (≥50pg/cell/day) reaching several grams/ L production. While costs are highly dependent on the productivity level, the need to accommodate the higher expression levels called for new approaches for purification technologies. Importance of introducing simultaneous improvements both in upstream and downstream processes will be discussed. More efficient and economical downstream process schemes employing high binding resins (up to 100mg/ml) and approaches to replace traditional Protein A purification schemes with non affinity processes using low cost resins for Hu Mabs production will be presented.

Alahari Arunakumari, Ph.D., *Director, Process Development,* **Medarex**

2:45 **Assessing Monoclonal Antibody Product Comparability following a Switch from Bovine to Recombinant Human Insulin in the Cell Culture Process**

A change in media raw material can impact the growth and productivity of the cells as well as the characteristics of the product produced by the cells. Laboratory scale and manufacturing scale studies were used to show that the monoclonal antibody produced using recombinant human insulin was comparable to that produced using bovine insulin.

Frank Maslanka, M.S., *Principal Scientist, Purification Technology, Global Biologics Supply Chain,* **Johnson and Johnson**

3:15 *Networking Refreshment Break*

3:30 **Current and Future Advances in Development of Downstream Processes for Purification of Monoclonal Antibodies**

Downstream processes will soon be required to rapidly recover and purify 50 kg lots in an economical and robust way. This presentation will focus on the capability of existing and future chromatography resins to handle such challenges from both a technical and economical perspective. Real application data from a recently introduced generation of resins will form the basis of the presentation.

Hans J. Johansson, M.S., *Senior Scientist,* **GE Healthcare,** *Sweden*

3 Cell Culture & Upstream Processing

4:00 **Bioburden Monitoring during Large-Scale Mammalian Cell Culture Manufacturing** Case Study

Bacterial contamination of CHO cultures constitutes one of the most significant operational risks to successful cell culture operations. Case studies of Wyeth BioPharma's experiences with bacterial contamination of large-scale CHO cultures as well as its strategies for implementing a scientifically rational bioburden-monitoring program will be presented.

Steven I. Max, Ph.D., *Principal Research Scientist, Cell and Molecular Sciences,* **Wyeth BioPharma**

4:30 **Sanitary Design Considerations for Large Scale Cell Culture Manufacturing**

Abstract unavailable at press date; please visit www.IBCLifeSciences/BPI/US for program updates.

Andrew Brewer, *Fermentation Technical Operations,* **Genentech, Inc.**

5:00 *Close of Conference*

Site Tour to Baxter BioScience's Hayward Facility
Wednesday, November 8, 2:00 pm • Open to First 50 Registrants

Get an inside view of the process development and manufacturing operations at Baxter BioScience's Hayward, California cGMP manufacturing facilities for mammalian cell culture products. This state-of-the-art, licensed facility includes 70,000 square feet of development and manufacturing space with 400 L, 1,500 L and 2,130 L stirred-tank and perfusion bioreactor systems, as well as disposable bioreactor systems for flexible manufacturing. Learn first-hand about Baxter's intensive yield-improvement programs, mature quality systems, and continuous improvement and operational excellence initiatives. Schedule:Leave Hilton San Francisco at 2:00 pm, return at 7:00 pm. Participants must wear closed-toe shoes.

Note space is limited to the first 50 conference registrants who choose this tour and register before September 15. You will be notified by September 29 reconfirming that there is a space for you on the tour. Please be sure to check off this option on the registration form.

4 Recovery & Purification

4:00 **Development and Scale Up of Disc-Stack Centrifugation Processes for Mammalian Cell Culture – The Impact of Cell Density and Cell Viability on Centrate Clarification Efficiency** Case Study

Centrifugation coupled with depth filtration is becoming the method of choice for removal of cells, cell debris, colloids, precipitates, aggregates, and other materials present in mammalian cell culture broth. A disc-stack centrifugation-based clarification process was developed for a mammalian cell culture broth. Optimization of the centrifugation step and selection of the depth filter media were balanced with cell culturing conditions to achieve target depth filter load. Development and optimization of the clarification process will be discussed.

Joseph Nti-Gyabaah, M.S., *Senior Research Chemical Engineer, Bioprocess Research and Development, BioPurification Development,* **Merck & Co.**

4:30 **Adapting Downstream Purification of Monoclonal Antibodies for the Challenges of High-Titer Cell Culture Processes without Radically Changing the Technology Base** Case Study

The seemingly relentless increase in expression levels of monoclonal antibodies from cell culture up to and beyond 5g/L continues to present significant challenges to downstream purification and the installed industry capacity within which those operations are based. This presentation will discuss the evolution of both standard antibody recovery technologies and process development paradigms that are allowing downstream operations to maintain pace with rising titres, for the present time at least.

Martin P. Smith, Ph.D., *Purification Development,* **Lonza Biologics, Plc.,** *United Kingdom*

5:00 *Close of Conference*

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Seminar #1

Characterization of Biologicals

Monday, November 6, 2006 • 2:00 pm -5:30 p.m. with break at 3:30

Seminar Instructor:

Barry Rosenblatt, Ph.D., *Director of Technical Services,* **Charles River Laboratories;** *President,* **SME Biotech Consultants**

Early and complete characterization of biologicals has increased in importance over the past few years. Aside from attaining the coveted "Well Characterized" by-line, early characterization has become an integral part of the "quality by design" initiative from the ICH, FDA and EMEA. Transitions from early stage to late stage clinical programs are also facilitated by increased attention to the biochemical and biophysical characteristics of early stage products. Technological advances in the application of traditional analytical methods have enhanced our ability to examine biological entities, including proteins, peptides, carbohydrates, lipids, and nucleic acids. The purpose of this workshop is to provide an overview of a characterization program for a typical biopharmaceutical product. This seminar will be directed towards development scientists in all fields of development, analytical sciences, manufacturing and QC.

Seminar #2

Preparing for Pre-Approval Inspections

Tuesday, November 7, 2006 • 8:00 am to 12:00 pm with break at 9:45

Seminar Instructors:

Sheila G. Magil, Ph.D., *Consultant, and* **Brian Turner, Ph.D.,** *Senior Consultant,* **BioProcess Technology Consultants, Inc.**

A Pre-Approval Inspection (PAI) is one of the last hurdles to commercial sale of a therapeutic product. This workshop is designed to give the participants some guidance on the challenges likely to be encountered during a PAI. Participants will learn how to prepare from both a strategic and tactical perspective. The focus will be on the scientific, manufacturing and quality "hot buttons." The workshop will follow the systems approach used by the FDA. This workshop will be of interest to Manufacturing, Process Development, Quality and Regulatory professionals.

Learn: What are the key documents
How to structure the visit
Which facilities are most likely to be inspected

Seminar #3

Introduction to Biopharmaceutical Manufacturing

Wednesday, November 8, 2006 • 8:00 am to 11:45 with Break at 9:45

Seminar Instructor:

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

This seminar provides a high level overview of the operations and equipment used in the manufacture of biopharmaceutical products. Beginning with a look at the physical and chemical structure of proteins and how we characterize and measure their properties, through the development of an expression system and cell bank, we explore the major process steps employed in the production of proteins, including fermentation and cell culture; recovery operations such as centrifugation, microfiltration and ultrafiltration; purification by chromatography techniques including ion exchange, hydrophobic interaction, reversed phase, affinity and gel filtration; sterilization, aseptic filling, and lyophilization. We conclude with a look at the design and operation of facilities in which biopharmaceuticals are manufactured.

For more details, visit www.IBCLifeSciences.com/BPISeminars

Seminars require separate registration from BPI Conference. See registration page for details.

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Sartorius is an international leader in process technology covering the segments of biotechnology and mechatronics. Sartorius specializes in the manufacture and support of separation and purification equipment scaleable from R&D to production levels. This includes process, pilot and laboratory filtration systems for pharmaceuticals and biotech industries, and a portfolio which includes membrane and depth filter cartridges, capsules, fermentors, bioreactors, crossflow micro and ultrafiltration systems, life science laboratory devices, cell culture products, sanitary housings and filter integrity test equipment, filter and bag assemblies as well as disposable mixing technologies.

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Exhibit Hall Hours

Monday, November 6 • 5:30 pm – 7:00 pm
Tuesday, November 7 • 9:45 am – 7:15 pm
Wednesday, November 8 • 9:45 am – 2:00 pm

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5. Mail – IBC USA Conferences, P.O. Box 414525, Boston, MA 02241-4525

Step One: Please complete the following to register

❑ **Please register me for BioProcess International™ Conference & Exhibition** B3165 FAX

Turn to back cover, find VIP code (above mailing address) and enter above.

NAME 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

Team Discount: Register 3, the 4th goes FREE!

When three members of the same company register for the conference at the same time, the fourth attends for FREE! Complete registration forms for all parties must be sent together with complete payments for the entire group to qualify for team discounts.
No partial payments or registrations sent without payment are eligible for this discount. Note: The free registration will be applied to the lowest conference fee option.

Step Two: Please select conference package

Industry Fees	On or before July 14, 2006	On or before August 11, 2006	On or before September 8, 2006	On or before October 6, 2006	After October 6, 2006
4-Day Pass (Mon-Thurs)* – *BEST VALUE*	☐ $1599	☐ $1699	☐ $1799	☐ $1899	☐ $1999
3-Day Pass* (Choose One: ☐ Mon-Wed OR ☐ Tues-Thurs)	☐ $1399	☐ $1499	☐ $1599	☐ $1699	☐ $1799
Academic/Government Fees	On or before July 14, 2006	On or before August 11, 2006	On or before September 8, 2006	On or before October 6, 2006	After October 6, 2006
4-Day Pass (Mon-Thurs)* – *BEST VALUE*	☐ $599	☐ $699	☐ $799	☐ $899	☐ $999
3-Day Pass* (Choose One: ☐ Mon-Wed OR ☐ Tues-Thurs)	☐ $499	☐ $599	☐ $699	☐ $799	☐ $899

**Please indicate which track you primarily plan to attend:*
☐ **1. Production and Economics of Biopharmaceuticals**
☐ **2. Scaling Up from Bench through Commercialization**
☐ **3. Cell Culture and Upstream Processing**
☐ **4. Recovery and Purification**

Do you wish to attend the Baxter Site Tour? ☐ **Yes** ☐ **No** (Space is limited to first 50 registrants)

Seminar Fees (Industry/Academic/Government)	One	Two	Three
Select Seminar(s)	☐ $299	☐ $499	☐ $599

Access not included with 3 or 4 day pass:
☐ #1 Protein Characterization
☐ #2 Preparing for Pre-Approval Inspections
☐ #3 Introduction to Biopharm Manufacturing

To Reserve a Posterboard	Commercial	Academic/Government
(space is limited)	☐ $50	☐ FREE

Exhibit Hall & Keynote Pass**	On or before October 27, 2006	After October 27, 2006
	☐ FREE	☐ $50

** You do not need to select this option if you are registering for the conference; it is included in your conference package. Select this option only if you are registering to attend the exhibit hall only.

For on-site registrations, please add $100

Step Three: Payment Information

Payment is required in advance of the conference

❒ Mastercard ❒ Visa ❒ American Express ❒ Check ❒ Wire Transfer **Total: $**_____

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 B3165, invoice number, person attending, name and date of the conference in the transfer instructions. Wire Transfers and EFT payments: Please contact accounts receivable at AR@ibcusa.com for banking details .

Card # Exp. Date

Name (as appears on card) Signature

Hotel, Venue and Travel Information

Hotel: **Hilton San Francisco, 333 O'Farrell Street, San Francisco, CA 94102 Ph: 415-771-1400 • Fax: 415-771-6807**

DISCOUNTED HOTEL RESERVATIONS: Please call the hotel directly before October 15, 2006, to be included in IBC's dedicated room block for this conference. Please be certain to mention IBC along with the conference title and date of the conference.

DISCOUNTED AIR TRAVEL RESERVATIONS: For all air travel arrangements, including International, please call or write IBC's official air travel agency, Commonwealth Travel Advisors, to book your travel via IBC's airline of choice, American Airlines. E-mail: jdwyer@traveladvisors.com or call: USA: 888-703-4286 or 508-366-3660; International: 508-366-3660. Please be certain to mention IBC along with the conference title, date and conference code B3165 when e-mailing or calling. Please note that there is a $29.00 booking fee for using this service.

Additional Registration Information

Unauthorized solicitation is strictly prohibited at this event and failure to comply could result in revokation of your access privileges. BioProcess International™ Conference and Exhibition 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. 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, two cocktail receptions, technology showcases, refreshments, access to exhibit hall and CD ROM with speaker documentation. 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: Should you be unable to attend for any reason, please inform IBC in writing prior to October 16, 2006 and a credit voucher for the full amount will be issued which must be used within one year of issuance. If you prefer, a full refund less a $395 non-refundable deposit will be issued. No refunds or credits will be given for cancellations received on or after October 16, 2006.

Substitutions of enrolled delegates may be made at any time. Please indicate upon registration whether you are eligible for a discount. No two discounts can be combined. If, for any reason, IBC decides to cancel this conference, IBC does not accept responsibility for covering airfare, hotel, or other costs incurred by registrants including delegates, speakers, sponsors, and guests. Program content subject to change without notice. The press may not quote speakers or delegates unless they have obtained their approval in writing.

Data Protection: The personal information shown on this form, and/or provided by you, will be held on a database and may be shared with companies in the 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 a disability or special dietary needs, please let us know in order that we may address your special needs for your attendance at this show. Please send your special needs via email at inquiry@ibcusa.com or fax 508-616-5522.