2nd

TECHNOLOGY TRANSFER FOR BIOLOGICS

Maintaining Quality, Speed and Flexibility in the Replication of Biologics Manufacturing as You Expand to New Molecules and Markets

October 5-6, 2015 | Hilton Boston Back Bay | Boston, MA

FEATURED SESSIONS:

MEDIMMUNE Grasps the Commercial Transfer Needs of Advanced Biologics

Brandon Christensen
Manager, Biopharmaceutical Tech Transfer and Manufacturing Support

GENZYME Uses Creative Models for Risk-Based Equipment Design

Zheng Huang
Senior Manager, Global Manufacturing Science and Technology

MERCK Emphasizes Transparency in Project Manager Skill Sets

John Bowers
Senior Principal Scientist, Biopharmaceutical Engineering

PFIZER Adjusts Technology Transfer Pipelines for Antibody-Drug Conjugates

Vincent Turula
Director, Biotherapeutics Outsourcing Management

BIOGEN IDEC Balances the Risks of Accelerated Tech Transfer

Tracy Ahrens
Tech Transfer Leader

*The **ONLY** event to focus specifically on the skill sets needed for managing, documenting and benchmarking quality control during every step of internal and outsourced tech transfer and scale-up.*

ALL-NEW CASE STUDIES ILLUSTRATE HOW TO:

- ☑ Identify the Unique Challenges of Transferring Processes for Biosimilars
- ☑ Adapt Your Biologics Transfer Tool Kit to New Molecular Types
- ☑ Accelerate Your Upscaling Methods for Well-Characterized Biologics
- ☑ Design Hybrid Facilities that Streamline Technology Transfers
- ☑ Cultivate Transparency and Cross-Discipline Expertise in Tech Transfer Project Managers

"Excellent, comprehensive presentations and case studies."

— Director, CMC Team Lead, **ALLERGAN**

"Strong content on technical requirements and challenges for method transfer, from obvious subject matter experts."

— Associate Director, External Manufacturing, **SHIRE**

For More Information Call 866–207–6528 or Visit www.exlevents.com/techtransfer

Dear Colleague,

All biotech manufacturing, processing, engineering and outsourcing professionals are responsible for maintaining biologic quality and avoiding contamination. This constant requirement spells the difference between success and failure, and it grows ever harder when you must duplicate and transfer your processes to new facilities — whether internal or external — and when upscaling to commercial biologic production. Missed deadlines in either of these processes can lead to unintended consequences and heavy costs for your company.

In addition to the longstanding challenges of biologics process transfer, the industry now faces more advanced obstacles in technical development and outsourcing. Most biotherapeutics are monoclonal antibodies, but increasingly more represent advanced types of molecules such as antibody-drug conjugates, which need greater care in their handling and transfer. At the same time, economic and capacity pressures have led to greater industry expansion into developing countries, where systemic maturity differences may put quality control and transparent documentation at risk.

ExL Events' **2nd Technology Transfer for Biologics** conference is the only event to focus specifically on developing the ideal skill sets, training, documentation and process practices to ensure biologics quality during and after method transfer. This year's program features all-new case studies built around our audience's most urgent questions, sharing best practices on how to:

- Establish **transparent and reliable communication and documentation** systems among tech transfer project managers and teams
- Proactively protect biologic quality when **changing raw material sourcing and manufacturing partners**
- Set the best balance for **permanent, single-use and hybrid facilities** when upscaling biologic production
- Adapt your biologic pipeline to accommodate **novel molecules such as antibody-drug conjugates**
- Bridge cultural and experience gaps when **transferring bioprocesses to developing countries**

Don't miss this opportunity to network with biomanufacturing leaders at this unique event dedicated to a skill set that is often overlooked yet crucial for your pipeline success!

We look forward to welcoming you to Boston this fall.

Sincerely,

Matt Greenbaum
Production Team Leader
ExL Events
mgreenbaum@exlevents.com

"Great examples of strategies to employ during technology transfer and methods to avoid wasted time and money."

— Associate Manufacturing Engineer, **MERRIMACK PHARMA**

WHO SHOULD ATTEND

This conference is designed for professionals from pharmaceutical organizations with the following responsibilities:

- **Technology Transfer**
- **Process Development**
- **Process Engineering/Process Sciences**
- **Quality Control/Quality Assurance**
- **Biotech Operations/Biologics Operations**
- **Biologics Outsourcing/Biologics Strategy**
- **Manufacturing/Clinical Manufacturing/ Biomanufacturing/CMC**
- **Facilities**
- **Upstream/Scale-Up**
- **Vendor Management/Supply Chain**
- **Analytical Development**

This event may also be of interest to:

- **CMOs**
- **CROs**
- **Lab Hardware Designers**
- **Facility Designers**
- **Cell Culture Suppliers/Managers**
- **Quality Control Specialists**

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To learn more about these opportunities, please contact Matt Halvorsen, Business Development Manager, at 917-258-5163 or mhalvorsen@exlevents.com.

HOTEL INFORMATION

HILTON BOSTON BACK BAY
40 Dalton Street
Boston, MA 02115

To make reservations, please call 617-236-1100 or 800-445-8667 and request the negotiated rate for **ExL's October Meetings.**. The group rate is available until **September 14, 2015**. Please book your room early as rooms available at this rate are limited.

For More Information Call 866–207–6528 or Visit www.exlevents.com/techtransfer

MONDAY, OCTOBER 5, 2015 // DAY ONE

8:00 REGISTRATION AND CONTINENTAL BREAKFAST

8:45 **CHAIRPERSON'S OPENING REMARKS**

Brandon Christensen, Manager, Biopharmaceutical Tech Transfer and Manufacturing Support, ***MEDIMMUNE***

NEW MOLECULES AND NEW ENVIRONMENTS FOR TECH TRANSFER

9:00 **LEVERAGE ANALYTICAL TECHNOLOGY PLATFORMS TO ACCELERATE PRODUCT AND PROCESS DEVELOPMENT AND TO MITIGATE RISKS ASSOCIATED WITH TECHNICAL TRANSFER**

Traditionally, the upscaling of biologics production involved stepwise increases in bioreactor size, checking at each level to observe product quality. But there may be circumstances where some of these intermediate steps can be omitted, especially if you are working with a particularly well-characterized monoclonal antibody. When can you accelerate upscaling by omitting intermediate steps, and what are the skill sets necessary to make sure quality doesn't decline?

- Map the different pathways for a 50-fold increase in bioreactor size
- Determine when bioreactor size multiplication will be acceptable
- Perform risk analysis to clarify how your scaling exercise will unfold

Hemant Kumar, Senior Director, Quality, ***GENZYME***

9:40 **MODIFY PIPELINES TO ADJUST TO NEW MOLECULES**

In the recent past, most of the biotech pipeline consisted of monoclonal antibodies. While these molecules are still significant, more companies have begun diversifying into new molecule candidates, such as antibody-drug conjugates, fusion proteins and bacterial cell cultures. What new methodologies are necessary to update your technology transfer skills for working with these molecules?

- Develop siting and relocating methods for molecules with unique transportation needs
- Adapt sending and receiving analytical methods for ADC challenges
- Grasp the clinical and commercial transfer needs for advanced biologics

Vincent Turula, Director, Biotherapeutics Outsourcing Management, ***PFIZER***

10:20 **CASE STUDY: THE UPSTREAM PERSPECTIVE FOR TECHNOLOGY TRANSFER OF NOVEL MOLECULES**

Manufacture of novel molecules is increasingly taking place in facilities traditionally oriented around monoclonal antibody cell cultures. This changeover brings with it new demands that require process design and equipment adaptation.

- Modify plant capabilities to accommodate the constraints associated with new molecules
- Evaluate the limits of traditional process boundaries
- Support adoption of new process alternativesd

Mark Meyers, Manager, Bioprocess Engineering, ***MEDIMMUNE***

11:00 NETWORKING BREAK

11:30 **CASE STUDY: SPECIAL CONSIDERATIONS FOR DOWNSTREAM NOVEL MOLECULE TECH TRANSFER**

As biologic pipelines diversify away from monoclonal antibodies, the rising emphasis on novel molecules is driving new methods of assessment and changes to tech transfer procedures.

- Assess fit-to-plant in light of increased process variability
- Understand and expand equipment capability
- Demonstrate feasibility of downstream transfer approaches

Brandon Christensen, Manager, Biopharmaceutical Tech Transfer and Manufacturing Support, ***MEDIMMUNE***

12:10 **PLAN FOR TECHNOLOGY TRANSFER AND SCALE-UP OF A BIOSIMILAR CELL CULTURE MANUFACTURING PROCESS**

Bench scale bioreactors are used during development of a biosimilar to adjust product quality attributes of the protein of interest to be "highly similar" to those of the branded product. Once these attributes have been established at the benchtop scale, the scale-up (either internal or external) requires that quality remain consistent with the branded product across all scales. In contrast to a new drug development program, a biosimilar is scaled with the intent that material will be manufactured using the final manufacturing process and ready for market. Though traditional parameters such as P/V, mixing time and set points are used for scale-up, a biosimilar process requires that these parameters and operating conditions be maintained in a narrow operating range usually tighter than is required for a new drug process.

- Manipulate biosimilar product quality with process levers to maintain similarity with the branded product
- Identify the unique challenges of transferring a biosimilar process to a CMO
- Solve the added complexities of working within a three-way partnership

Brett Belongia, Associate Director, Biologics Development, ***MOMENTA***

12:50 **CLARIFY TECHNIQUES TO ACCOMMODATE HIGHER DENSITIES AND TITERS FOR UPSTREAM-TO-DOWNSTREAM TRANSFERS AND UPSCALING**

Throughout the biotech industry, cell densities and protein titers are getting steadily higher, which places more pressure on process robustness downstream and adds to the risk of product impurities. This increased downstream burden, combined with scale-up considerations, can cause extra process stresses. Development scientists must be adept at all the technological tools for maintaining quality control.

- Utilize alternate clarification techniques to reduce product impurities and enhance separations
- Proceed with purification techniques typical to traditional processes
- Learn from case studies on both bacterial fermentation and mammalian cell cultures

Kathryn Golden, Senior Scientist, Manufacturing and Process Sciences, ***ELEVEN BIOTHERAPEUTICS***

1:30 LUNCHEON

PARTNERSHIPS, PROJECT MANAGEMENT AND PREPARATION FOR TECH TRANSFER

2:30 **BUILD MODELING TOOL KITS TO FACILITATE PROCESS ADAPTATION AND TECHNOLOGY TRANSFER**

How can refinements to your modeling techniques lead to more streamlined technology transfers? A good operational model can pre-empt potential bottlenecks in your GMP campaigns, and can also clarify how the equipment in your facility can best be leveraged to support operations. CFD and first principles modeling approaches were tightly integrated in overall Quality by Design approaches. Off-the-shelf software, home-growth model and innovative experimental techniques are combined to generate pragmatic yet creative solutions to successful process adaptation.

- Leverage CFD, operational and first principles models for science and risk-based equipment, process, and facility design
- Look deeper into various technology transfer phases to avoid discovering problems too late
- Use model and small-scale data to define the operation space for at-scale equipment, and get right-first-time results during engineering campaigns

Zheng Huang, Senior Manager, Global Manufacturing Science and Technology, ***GENZYME***

3:10 **EMPHASIZE COMMUNICATION AND TRANSPARENCY IN PROJECT MANAGER SKILL SETS**

Cross-team colleagues may be reluctant to critique each other or admit to gaps in their own knowledge. The best managers establish a non-punitive atmosphere in which members can comfortably disclose concerns.

- Explore the feasibility and pros and cons of full-time devoted technology transfer project managers
- Invite crucial feedback from upstream, downstream, analytical and formulation team representatives
- Benefit from merging cross-disciplinary expertise on manufacturing and regulatory expectations

John Bowers, Senior Principal Scientist, Biopharmaceutical Engineering, ***MERCK***

3:50 NETWORKING BREAK

4:20 **PROCESS FIT TO PLANT IMPACT ON PROCESS DEVELOPMENT LIFE CYCLE MANAGEMENT, EQUIPMENT STANDARDIZATION AND CMC SUCCESS**

Successful implementation of a process at scale is a CMC program success indicator. Process Fit to Plant (PFP) exercises can define process development targets and maximize the likelihood of technology transfer success. For an organization with a network of facilities across different scales, the usefulness of PFP depends a great deal on the level of equipment standardization.

- Examine how equipment standardization can be achieved
- Grasp relevance of standardization to operations and CMC success
- Ensure proficiency with PFP techniques

Amos Tsai, Principal Scientist, ***JOHNSON & JOHNSON***

5:00 **ENSURE EARLY QA INVOLVEMENT AND THE USE OF QUALITY IMPROVEMENT TOOLS TO INCREASE THE LIKELIHOOD OF TECH TRANSFER SUCCESS**

Your QA team should get involved with technology transfer proposal reviews from the very earliest stages. PDA Technical Report 65 described best practices for future technology transfers, and you can build a bespoke process around your needs using these practices as a road map for both internal and outsourced transfers.

- Use Six Sigma quality improvement tools to identify key processes and requirements specific to your project
- Create processes more likely to succeed
- Identify and learn from past instances where QA teams were invited too late — at the interim or even the final review

Amnon Eylath, Senior Director, Quality Assurance, ***GENZYME***

5:40 END OF DAY ONE

TUESDAY, OCTOBER 6, 2015 // DAY TWO

8:00 REGISTRATION AND CONTINENTAL BREAKFAST

8:45 **CHAIRPERSON'S RECAP OF DAY ONE**

Brandon Christensen, Manager, Biopharmaceutical Tech Transfer and Manufacturing Support, ***MEDIMMUNE***

9:00 **BALANCE THE RISKS, SPECIALIZATIONS AND STANDARDIZATIONS REQUIRED TO EXECUTE AN 8-WEEK TECH TRANSFER**

Billion-dollar site depreciation is expensive. Speed introduces risk. So how do you maximize facility utilization and balance limited resources to support a high velocity for tech transfers? Learn how Biogen successfully executes on a multi-product production schedule ranging from first-in-human, clinical, commercial and CMO programs.

- Understand phase-appropriate definitions of success for clinical versus commercial production
- Manage CMO relationships and platform process development
- Transfer process-operating parameters with known process knowledge gaps with speed, accuracy and flexibility

Tracy Ahrens, Tech Transfer Leader, ***BIOGEN IDEC***

9:45 **BUILD A DECISION TREE THAT OPTIMIZES FLEXIBILITY AND SPEED IN TECHNOLOGY TRANSFER**

Many biologics companies chase similar therapeutic targets and markets, so being the first to market is critical. One of the most basic and unchanging needs for biologics manufacturers is to decrease production time without compromising quality.

- Structure your facility choices to allow for the best potential manufacturing pipeline
- Survey the competitive landscape in line with corporate priorities to determine which molecules to manufacture and whether to keep technology transfers internal or outsourced
- Fit your processes to your plant assessment to be sure that your facilities can handle the necessary transfers

Fauad Hasan, Director, CMC Teams, ***ALLERGAN***

10:30 NETWORKING BREAK

11:00 **MANAGE YOUR TECHNOLOGY TRANSFERS WITH AN EMPHASIS ON SYSTEM ROBUSTNESS**

When you transfer from one CMO to another, you may find yourself having to upscale processes at the same time. If you transfer at an early stage, you may have little data or non-robust systems and your vendor may not be able to meet your raw materials needs.

- Make process changes as needed based on gaps in facility capacity
- Transition to larger-scale vendors who can overcome raw material challenges
- Maintain flexibility with analytics, skill sets and the outcomes of processes

Stephen Gacheru, Project Lead, TPM Group, ***BRISTOL-MYERS SQUIBB***

11:45 **GRASP THE IMPORTANCE OF PHASE 0 — PRELIMINARY FEASIBILITY ASSESSMENTS ON RU AND SU BEFORE YOU LAUNCH A TRANSFER PROJECT**

As every technology transfer project involves two parties (SU and RU), it is important to ensure that each satisfies key prerequisites before initiating the project. It is critical to select suitable receiving units based on thorough technical, compliance, regulatory and business assessment.

- Establish business contracts, service agreements or supply agreements with any third parties proposed for target transfers
- Prepare a Quality & Technical Agreement (QTA) on site-to-site or company-to-company transfers
- Verify adequate product and process knowledge and analytical technology at SU to enable the transfer

Yan Fang Ma, Senior Director, Technology Transfer, ***SANOFI PASTEUR***

12:30 LUNCHEON

1:30 **ADVANCE FROM LEGACY PRODUCT STANDARDS TO NEXT-GENERATION PROCESSES**

The majority of all biologics in the industry's pipeline today are monoclonal antibodies, which allows for the adoption of similar generic platforms. But legacy products, in development for 10 years or more, inherit older processes that are not as robust. While it is typical to expect that commercial-ready processes are the most mature and are capable of a generic approach, using older legacy processes requires constant management and triggers a debate on whether to launch a second generation.

- Weigh the pros and cons of updating legacy processes
- Quantify the requirements, in both time and money, for refiling processes in multiple global markets
- Determine when the savings in process problems and costs outweighs the regulatory challenges after an update

Gene Mehr, Senior Engineer II, ***BIOGEN IDEC***

2:15 **BUILD A SENSE OF INVESTMENT IN TEAM MEMBERS TO AVOID INFORMATION SLOWDOWNS**

Successfully matching your lab scale production with clinical and commercial scales requires much more than filling out documents or monitoring technical parameters. To drive success you must establish a sense of ownership within process developers and manufacturers, so every stakeholder works together to establish a system that can run on scheduled meetings.

- Establish process walkthrough schedules and regular group record sign-offs
- Transition from a "box-checking" mentality to one that equips teams to understand and react to nuances
- Empower your teams to rapidly adjust to changes in a manner better than an educated guess

Venkat Koganti, Associate Director, Formulation and Process Development, ***CELSION CORPORATION***

Jenna Carlson, Senior Technical Manager, ***GENENTECH***

3:00 CONFERENCE CONCLUDES

REGISTRATION INFORMATION

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866-207-6528

888-221-6750

ExL Events, Inc.
494 8th Avenue, Fourth Floor
New York, NY 10001

MEDIA PARTNERS

Registration fees for attending ExL's 2nd annual Technology Transfer for Biologics conference:

EARLY BIRD PRICING *Register Before Friday, August 21, 2015*	$1,895
STANDARD PRICING *Register After Friday, August 21, 2015*	$2,095
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QUESTIONS? COMMENTS?

Do you have any questions, comments on the program, or specific topics you would like addressed? Would you like to get involved as a speaker, moderator or discussion leader? Please email the Production Team Leader, Matt Greenbaum at mgreenbaum@exlevents.com.

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