

6th

TECHNOLOGY TRANSFER FOR BIOLOGICS CONFERENCE

Improve Partnerships and Reduce Risk Within the Replication of Biologics While
Enhancing Speed, Maintaining Quality, and Ensuring Flexibility

September 23-24, 2019 // Hyatt Regency Boston Harbor // Boston, MA

The **ONLY**
educational event in
the U.S. specifically devoted
to Technology Transfer



KEY TAKEAWAYS

1. Explore strategies to reduce cost, mitigate risk, and increase tech transfer success rate
2. Examine technical applications such as an analytical method of transfers, project definition, and gap analysis
3. Determine best practices for partnering with CMOs through the selection process and management
4. Align key objectives among stakeholders in order to ease communication and solidify processes
5. Compare and contrast formal process transfer against faster, more innovative ways to transfer
6. Discuss the future of tech transfer regarding new technologies and their anticipated application

SPECIAL FDA PRESENTATION BY:

Yolanda Hawkins, Ph.D., M.B.A., *Technology Transfer Specialist - Center for Drug Evaluation and Research (CDER), FDA*

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KEYNOTE SPEAKER



Adnan Sabir,
*Principal Consultant, Pharma Consulting Services,
Former Associate Director of QA,*
KOWA PHARMACEUTICALS



Jonathan Romero,
Director, Biologics Development and Manufacturing,
CELGENE



Jim Leverone,
Senior Engineer, Manufacturing Sciences,
IMMUNOGEN



Jody Logan,
Senior Manufacturing Technical Specialist,
GENENTECH



Mitch Goetz,
Senior Engineer II,
BIOGEN



Magdalena Leszczyniecka,
Chief Executive Officer, President,
STC BIOLOGICS



Daniel Rudolph, Ph.D.,
Principal Engineer, Manufacturing Development, BioDefense Division,
EMERGENT BIOSOLUTIONS

FEATURED SPEAKERS

To Register, Call 201 871 0474 or Click Here

6th TECHNOLOGY TRANSFER FOR BIOLOGICS CONFERENCE

Who Should Attend

This conference is designed for representatives from pharmaceutical and biotechnology companies with responsibilities in the following areas:

- > Technology Transfer
- > Process Development/Process Engineering/Process
- > Sciences/Bioprocessing
- > Biotech Operations/Biologics Operations
- > Manufacturing/Clinical Manufacturing/Bio manufacturing/CMC
- > Quality Control/Quality Assurance
- > Biologics Outsourcing/Biologics Strategy
- > Project/Program Management
- > Upstream/Downstream/Scale-Up
- > Vendor Management/Supplier Management/Supply Chain
- > CTO
- > Packaging/Labeling
- > Technical Manager
- > Technical Support Manager
- > Manufacturing Sciences and Technology

This conference is also of interest to:

- > CMOs/CDMOs
- > Technology Transfer/Commercialization Software
- > Facilities/Engineering Specialists
- > Lab Hardware/Reagent Providers
- > Tech Transfer/Quality Control/Process Specialists

Sponsorship and Exhibition Opportunities

Do you want to spread the word about your organization's solutions and services to potential clients who will be attending this event? Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event or distribute promotional items to attendees. ExL Events will work closely with you to customize a package that will suit all of your needs.

Dear Colleague,

In order to ensure the success of biologic technology transfers, it is important to understand the importance of strong project management, engineering, validation, and QA/QC. Without ensuring full collaboration and utilizing the entire spectrum, errors and risk are allowed into the process, thus reducing accuracy and precision.

ExL's 6th Technology Transfer for Biologics Conference will provide attendees with an unmatched opportunity to study and improve fundamental, day-to-day functions within the tech transfer process. As the only educational U.S. event solely devoted to the project, facility, and partnership management skills needed to maintain biologics quality in every step of the process, we are certain you will walk away with actionable insights and information to share with your colleagues.

Attendees will gain insight into:

- > Increased success rates for tech transfer through risk and cost reduction tactics
- > Identification of technical applications, tools, resources, and analytical methods
- > Improvements to partnerships with outsourced vendors and strengthened communication
- > Advancements and applications of processes within cell and gene therapies

...and much more!

I look forward to seeing you in Boston this Fall!

Sincerely,

Monica Bulnes

Monica Bulnes
Conference Production Director

Hyatt Regency Boston Harbor

101 Harborside Dr, Boston, MA 02128

To make reservations, call 1-888-421-1442 and request the negotiated rate for **ExL's September Meetings**. You may also make reservations, online using the following weblink: <https://bit.ly/2veAFs4>. The group rate is available until **September 3, 2019**. Please book your room early, as rooms available at this rate are limited.

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8:00 Registration and Continental Breakfast

9:00 **Chairperson's Opening Remarks**

9:15 **KEYNOTE SESSION: "Ten Commandments" — The Keys to a Seamless Technology Transfer**

A seamless technology transfer is desired by all but difficult to achieve in most cases due to poor planning. Set the tone for the next two days with these "ten commandments" that should aid in preparing a successful tech transfer plan.

- Determine a plan for what should ensure a successful tech transfer using ten key rules
- Discuss the trio of ICH guidelines Q8, 9, and 10, with an emphasis on risk analysis to build quality into a product
- Increase confidence for releasing a product commercially: Explore the benefits to optimization/scale-up
- Understand the risk of miscommunication with CDMOs

Adnan Sabir, *Principal Consultant, Pharma Consulting Services, Former Associate Director of QA, KOWA PHARMACEUTICALS*

KEYNOTE

10:15 **QbD Tech Transfer to Streamline Cell Therapy Development Across Multiple Sites**

- Explore the opportunity to incorporate QbD tech transfer into cell therapy manufacturing
- Address alignment and communication efforts between receiving and transferring sites for a smooth tech transfer
- Manage the application of quality by design principles and project management
- Establish key performance indicators to reduce risk and increase process success rate

Russell Beste, *Sr. Director Global Process Development, MYLAN*

11:00 Networking Break

11:30 **A Road Map to Collaboration and How to Overcome Obstacles Throughout the Tech Transfer Process**

- Follow the tech transfer process by hearing from multiple professionals involved in different stages of the process
- Understand interconnectivity of activities and groups and learn tactics to assure collaboration across all departments
- Address errors that are made and the implications it may have on the transfer success or timeline
- Strengthen your overall tech transfer process by employing best practices

Moderator:

Jim Leverone, *Senior Engineer, Manufacturing Sciences, IMMUNOGEN*

12:30 Luncheon

1:30 **Streamline the Manufacturing Process of Biologics to Reduce Risk and Ensure Efficiency**

- Discuss new ways of approaching antibody development
- Explore ways in which smaller biotechnology companies achieve a faster transfer without formal processes
- Evaluate challenges in analytical tech transfer with the help of case studies dissecting flaws and successes
- Overcome missing information throughout the process while ensuring higher quality

Magdalena Leszczyniecka, *Chief Executive Officer, President, STC BIOLOGICS*

Dr. Zahra Shahrokh, *Chief Development Officer, STC BIOLOGICS*

2:15 **Address Complications in CMO Relationship Establishment to Strengthen CMO-to-Client Connections**

- Discuss how to establish upfront transparency on expectations across both client and CMO including interpretation of quality and service agreements
- Open dialogue with your CMO to ensure clear knowledge of operational capabilities and lessons learned to enhance supply outcomes while helping the client understand potential upfront TT bottlenecks
- Establish how to manage and communicate internal client business needs and timelines most effectively while prioritizing CMO internal and client challenges to strengthen the outcome
- How to apply key technology transfer concepts to new modalities with the cell and gene therapy operational space
- Case Study: Explore past hurdles and how tools for data trending, process trending, and management can be leveraged for future success

Jonathan Romero, *Director, Biologics Development and Manufacturing, CELGENE*

3:15 Networking Break

3:45 **Remember When Engineering and Clinical Runs Were a Thing? Case Study: Direct Tech Transfer to Process Performance Qualification (PPQ)**

- Experience an in-depth review of a tech transfer and scale-up of a partner process to the 15K scale for PPQ
- Discuss challenges and successes with facility fit, risk mitigation, readiness, and manufacturing operations
- Explore project management details for project completion including scope of work, milestones, performance
- Interpret areas of improvement and lessons learned to ensure future growth

Mitch Goetz, *Senior Engineer II, BIOGEN*

Carin Gray, *Senior Engineer II, BIOGEN*

4:45 Day One Concludes

8:00 Registration and Continental Breakfast

9:00 **Chairperson's Opening Remarks**

9:15 **Explore Methods to Leverage an Accelerated Technology Transfer**

- Gain a full understanding of technical requirements key to the manufacturing of biologics
- Ensure a smooth and regulated accelerated process utilizing certain process methods
- Identify SOP essential to accelerate processes and improve existing procedures

Jody Logan, Senior Manufacturing Technical Specialist, **GENENTECH**

10:15 **Technology Transfer of Biological Processes Suitable for Rapid Response for Single-Use Facility**

- Discuss rapid response approaches to addressing pandemics
- Evaluate challenges and defining success in rapid technology transfer and development
- Case study: Technology transfer with single-use equipment processes

Daniel Rudolph, Ph.D., Principal Engineer, Manufacturing Development, BioDefense Division, **EMERGENT BIOSOLUTIONS**

11:15 Networking Break

11:45 **A Holistic Approach to the Management Process From Transfer to Manufacturing**

- Ensure a thorough transfer of technology through a variety of management techniques
- Explore late stage process development and requirements for success
- Address challenges when scaling up and how to overcome difficulties

Claudia Buser, Scientific Director, **SANOFI GENZYME**

12:30 **A Regulatory Perspective: Government Technology Transfer Transactions**

FDA SPOTLIGHT

- Discuss protection of proprietary information, press releases, and nondisclosure agreements and ensure a template of agreements to maintain privacy throughout the tech transfer process
- Case Study: Explore examples of a variety of agreements executed by a regulatory body
- Ensure a safe and effective technology transfer thus improving success rates and minimizing risks

Yolanda Hawkins, Ph.D., M.B.A., Technology Transfer Specialist - Center for Drug Evaluation and Research (CDER), **FDA**

1:15 Luncheon

2:15 **How to Remain Agile and Maximize Successful Tech Transfers With the Help of Your CDMO**

- CDMO and customers for maximum communication and transparency
- Standardize tech transfer by developing global policies to align and drive success across multiple manufacturing sites
- Utilize tech transfer protocols, tools, and platforms to increase speed and reduce costs
- Discuss project management tailored to leverage standard stage gates and risk-based assessments
- Address challenges when leveraging single-use platforms but also embracing opportunities for delivering reduced risk in commercial-grade manufacturing

Mark Ramsey, Senior Manager MSAT, **THERMO FISHER SCIENTIFIC**

3:15 **CASE STUDY: The Upstream Perspective for Technology Transfer of Novel Molecules**

- Adjust to new demands of process design and equipment adaptation essential to the manufacturing of novel molecules
- Modify plant capabilities to accommodate the constraints associated with new molecules
- Evaluate the limits of traditional process boundaries
- Support adoption of new process alternatives

4:00 **Closing Remarks**

"I received a holistic insight into tech transfer! It is undervalued at my company, but I got a lot of information to help higher-ups understand its importance."

—MSAT, Tech Transfer Specialist, **BioMarin**

"Excellent sessions. Very well planned and essential to understanding perspectives. Very applicable to multiple levels of tech transfer."

—Director, Engineering, Marketing and IOT, **Cognizant**

"Excellent, interactive, and thought-provoking. It was wonderful working with other people and seeing how others interpret the same ideas."

—QA Associate, **Regeneron**

To Register Click Here, or

Mail Directly To:

PMA Conference Management
PO Box 2303
Falls Church VA 22042
201 871 0474
Fax 253 663 7224
register@pmaconference.com

Registration Fees for Attending ExL's 6th Technology Transfer for Biologics Conference

EARLY BIRD PRICING <i>Register by Friday, August 10, 2019</i>	STANDARD PRICING	ONSITE PRICING
\$1,895	\$2,095	\$2,195

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Save 25% per person when registering four

Save
25%

For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four at one time). This is a savings of 25% per person.

Save 15% per person when registering three

Save
15%

Can only send three? You can still save 15% off every registration.

Offers may not be combined. Early Bird rates do not apply. To find out more about how you can take advantage of these group discounts, please call 201 871 0474

Questions? Comments?

Do you have a question or comment that you would like addressed at this event? Would you like to get involved as a speaker or discussion leader?

Media Partners



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