

ISPE Boston Area Chapter Presents:

Biotech Process Scale-up & Tech Transfer: Everything You Need to Know for Success the First Time

Tuesday, January 26, 2010

Foley Hoag LLP

Seaport World Trade Center West
155 Seaport Boulevard, Boston, MA 02210-2600



**Boston Area
Chapter**

ENGINEERING
PHARMACEUTICAL
INNOVATION

Attendees will discover the complexities of biopharmaceutical manufacturing processes and the challenges of transferring processes from development laboratories to cGMP production or from early stage production to the larger scales and greater compliance required for later stages. The analytical, process, management, and governance tools that are essential to facilitate effective tech transfer in biotechnology will be revealed by speakers who have worked first-hand in this area and who know what the challenges and solutions are.

PRESENTATION ONE:

What a tech transfer needs to accomplish, hurdles and techniques

Every Technology Transfer Project has a core set of objectives that must be met to achieve success. The process must be transferred faithfully and compliantly, with as few changes as possible to minimize scale-related issues. This presentation will identify core objectives for tech transfer. Success is also predicated on the pre-existence of a management-endorsed governance structure, so an example of governance and utilization of an empowered team structure will also be presented. It will highlight some keys to success and focus on some common pitfalls that can lead to delay and rework. For companies acting in the role of Contract Manufacturing Organization, the objectives are the same, but the interpersonal dynamics between the donor organization and the CMO recipient are different and will be considered.

SPEAKER ONE:

Jeff Socolow, Senior Project Manager, Shire Human Genetic Therapies

Jeff Socolow, MBA is a Senior Project Manager at Shire Human Genetic Therapies, Inc. in Cambridge, MA. He manages a group of Project Managers focused on internal clinical drug substance tech transfers from Shire process development to commercial manufacturing and transfers from its licensed commercial facility in Cambridge to the new Atlas commercial facility in Lexington, MA. He has spent his entire career in Boston-based biotechnology firms, starting with Collaborative Research, Inc. in the eighties, Therion Biologics, Inc., ImmuLogic Pharmaceuticals, Inc., and most recently, 10+ years at Wyeth Biotech, Inc. in Andover, MA. Most of his career has focused on mammalian cell bioreactor process development, with experience developing processes using E. Coli, insect cells, and viral vaccine production. The last 8 years have been spent focused on commercial biotech manufacturing project management, with an emphasis on process technology transfer, from internal PD to commercial manufacturing and facilitation of technology transfers from the CMO recipient standpoint. Mr. Socolow holds a BS in Biology from the University of Massachusetts at Amherst and an MBA from Bentley University in Waltham, MA.

PRESENTATION TWO:

What needs to be done before a tech transfer starts

Technology Transfer is a key activity in the manufacture and testing of biopharmaceuticals. Due to the complexity of biologics it can also be a challenging task. Having the right information before beginning transfer can increase the success rate of transfer. This talk will focus on the information needed before transfer begins. It will also identify the additional information that can be obtained during the transfer activities.

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SPEAKER TWO:

Sheila Magil, PhD, BioProcess Technology Consultants

Sheila Magil, PhD, (BioProcess Technology Consultants) has over 20 years of experience in analytical method development for small molecules, peptides and biologics. Her expertise includes quality, protein chemistry, and formulation development. She was formerly Sr. Manager of Analytical Development and QC at Biomeasure, Inc., and previously held positions at Waratah Pharma, Alkermes, Bion, and HHMI at Mass. General Hospital. Dr. Magil has implemented quality systems and has managed external analytical and QC activities for multiple biopharmaceuticals. Dr. Magil holds a PhD in Biochemistry from the University of Minnesota.

PRESENTATION THREE:

Case Study: New Process involving a therapeutic protein in E coli from 5L to 1000L+

A scaleable process to produce a therapeutic protein in E coli was developed at the 5L scale. Unit operations and operating parameters that are readily transferrable to the GMP manufacturing scale (1100L) were selected and optimized at the development scale. Multiple process integration runs were performed at the development scale prior to transfer to GMP manufacturing, and the allowable operating parameters at that scale defined the process design space. Upon transfer to large scale GMP manufacturing, some unit operations did not perform as anticipated and these operations, along with solutions for future process development and scale up, will be described and evaluated in detail.

SPEAKER THREE:

Susan Dana Jones, PhD, BioProcess Technology Consultants

Susan Dana Jones, PhD, (BioProcess Technology Consultants) has more than 20 years of discovery, product development, and strategic planning experience in biotechnology. She co-founded two biotechnology companies and has managed discovery and product development programs in multiple organizations and for multiple disease areas. She currently manages several outsourced biopharmaceutical process development and manufacturing programs for client products. In addition, Dr. Jones serves as Vice President of Research and Development for ImmuRx, a New Hampshire based start up company, a member of the Board of Directors of Virginia-based start-up company Gene Solutions, and as a member of the Editorial Advisory Board of BioProcess International. Prior to joining BioProcess Technology Consultants, Dr. Jones was Senior Vice President of Corporate Development at Serenex, Inc. She previously held positions at Waratah Pharmaceuticals, Virus Research Institute, IntraImmune Therapies Inc., and Dyax Corp. Dr. Jones holds a Bachelor's degree from Harvard University, and a PhD from the University of California, San Francisco.

MEETING MANAGER:

Phillip Werth, Shire HGT
Joyce Chiu, Perceptive Informatics

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PROGRAM SCHEDULE:

Registration: 5:30 PM – 6:00 PM
Reception: 5:30 PM – 6:30 PM
Presentations: 6:30 PM – 8:30 PM

*A networking reception, with hors d'oeuvres, will be held **BEFORE** the presentation.*

REGISTRATION IS NOW OPEN ONLINE!

Don't waste time filling in the form! Register online at www.ISPEBoston.org/Events.
Pay by credit card OR check.

REGISTRATION FEES:

	Registration by 1/19/2010:	After 1/19/2010:
<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Non-members	\$95	\$115
<input type="checkbox"/> Students	\$5	\$10

**** PLEASE NOTE: CANCELLATIONS RECEIVED AFTER Jan 19, 2010 ARE SUBJECT TO BILLING ****

Name: _____ Title: _____

Do you wish to opt out of being listed on the attendee roster?

Company: _____ Member #: _____

Address: _____ City: _____ State: _____ Zip: _____

Tel: _____ Fax: _____ Email: _____

PAY BY CREDIT CARD: Type: Visa MasterCard AMEX

Card #: _____ Expiration Date: _____

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Telephone: 781-647-ISPE (4773) • Fax: 781-647-7222 • Email: ispe@camihq.com

DIRECTIONS:

Foley Hoag LLP, Seaport World Trade Center West, 155 Seaport Boulevard, Boston, MA 02210-2600

From the North

Follow Interstate 93 South to Exit 23/Purchase Street. Once On the exit ramp, get into the left lane and turn left onto the Seaport Blvd/Evelyn Moakley Bridge. Continue on Seaport Blvd over the Evelyn Moakley Bridge for approximately .8 miles. 155 Seaport Boulevard/Seaport West building will be immediately to your right. The Seaport Boulevard entrance to the Seaport Garage will be on the right, just past the Seaport Boulevard/B Street intersection. The building entrance is located on B Street (facing the city).

From the South

Follow Interstate 93 North to Exit 20, Massachusetts Turnpike/Logan Airport. Once on the exit ramp follow signs for South Boston, staying in the right lane through the tunnel. At the first set of lights at the end of the off-ramp, take a right onto Congress Street. Once on Congress Street, move towards the far left lane and at the first set of lights, take a left onto B Street. 155 Seaport Boulevard/Seaport West is directly adjacent to the right. To access parking, follow B Street to the end and take a right at the lights onto Seaport Boulevard. The Seaport Boulevard entrance to the Seaport Garage will be immediately on the right. The building entrance is located on B Street (facing the city).

From the West via Storrow Drive

Take Storrow Drive East to Leverett Circle and follow signs for Interstate 93 South/Logan International Airport. Follow directions from the North.

From Western Massachusetts and the Massachusetts Turnpike

Follow the Massachusetts Turnpike/Interstate 90 East to Exit 25, South Boston. Stay to the left of the fork on the off-ramp, following signs for Seaport Boulevard. Continue straight through the first set of lights at the end of the off-ramp, and proceed straight onto East Service Road. At the next set of lights, take a right onto Seaport Boulevard. Follow Seaport Boulevard through the next set of lights. 155 Seaport Boulevard/Seaport West is directly adjacent to the right. The Seaport Boulevard entrance to the Seaport Garage will be on the right, just past the Seaport Boulevard/B Street intersection. The building entrance is located on B Street (facing the city).

Access to Seaport West and Foley Hoag Lobby

The lobby to Seaport West may be accessed from B Street. Foley Hoag's main reception is on Floor 16.

Seaport Hotel Garage Parking Rates

0-1 hour \$9.00; 1-10 hours \$17.00; 10-24 hours \$28.00

