

ISPE Boston Area Chapter presents:

Facility Tour & Dual-track Seminar

Facility Tour – The New WPI Bioengineering Center

Track 1: Process Validation – Practical Aspects of the New Guidance

Track 2: Biotech 101 – Empowering You with the Basics of Biopharmaceuticals

Thursday, April 18, 2013

WPI Gateway Park

60 Prescott Street

Worcester, MA 01605



**Boston Area
Chapter**

TRACK 1: Process Validation – Practical Aspects of the New Guidance

In January 2011 the FDA issued new Guidance for Industry on Process Validation, which replaced guidance issued over 20 years ago. The FDA Guidance is intended to align Process Validation practices with a “lifecycle” concept as well as with the principles outlined in ICH Guidelines Q8 (Pharmaceutical Development), Q9 (Quality Risk Management), and Q10 (Pharmaceutical Quality Systems). This session will review the FDA Guidance just issued, and will summarize the efforts of ISPE’s Process Validation Implementation Team, including some practical considerations for implementing the new approach. In addition, observations from establishing a Stage 3 “Continued Process Verification” program for legacy products will be shared, including challenges and lessons learned.

SPEAKER:

Rusty Morrison, Commissioning Agents, Inc

Rusty (Russell) Morrison is the Director of Process and Technical Services for Commissioning Agents, Inc., where he is responsible for the sales, marketing, and execution of process validation and technology transfer projects. He has directed multiple process validation efforts, including the complete process validation for the startup of a large cell culture monoclonal antibody manufacturing facility, and remedial process validation for a manufacturer of numerous small volume sterile parenteral products, including designing a continued process verification program.

Mr. Morrison is a member of PDA and ISPE, and is currently serving as a member of ISPE’s Process Validation Implementation Team. In addition, he is a past president and current board member of the PDA New England Chapter. Prior to Commissioning Agents, Mr. Morrison held management / engineering positions with Protein Sciences Corporation, INNCOM International, and Sonalysts, Inc., and served as a submarine officer in the United States Navy. He has a BS in chemical engineering with honors from the University of Minnesota and an MBA in Information Systems from Rensselaer Polytechnic Institute.

TRACK 2: Biotech 101 – Empowering You with the Basics of Biopharmaceuticals

What goes on inside a biotech manufacturing facility? How are these lifesaving drugs actually made? What is upstream? What is Downstream? ISPE’s Boston Area Chapter is bringing you the answers to these questions and much more in their Biotech 101 session at WPI. In this session, we will show you the process of how biotech based drugs are made, the typical systems required to maintain a robust facility, and the critical quality attributes and process parameters associated with manufacturing. No matter what your experience level, this behind the scenes look into drug manufacturing will enhance your understanding of how a single cell is turned into a lifesaving therapy.

SPEAKER:

Alex Cardoso, Biogen Idec

Alex Cardoso is a Process Engineer at Biogen Idec, where he is responsible for the process support, equipment design and technology transfer projects. He has been a technical lead on all scales of production, taking processes from the initial small scale into large commercial scale, including process validation. His experience includes both mammalian and microbial production as well as both upstream and downstream activities.

Prior to joining Biogen Idec, Mr. Cardoso held positions in manufacturing/engineering with Lonza, CRC Consulting, and Amgen. He has a BS in Chemical Engineering from the University of Massachusetts Amherst and is a member of ISPE.

MEETING MANAGER:

Andrea Massa, Burkert Fluid Control Systems

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Connecting a World of
Pharmaceutical Knowledge

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PROGRAM SCHEDULE

Registration:	5:30 PM – 6:00 PM
Networking Reception and Facility Tour:	5:30 PM – 6:30 PM
Presentations (Track 1 and Track 2 run concurrently):	6:30 PM – 8:30 PM

REGISTRATION FEES:

	Registration by 4/11/13	After 4/11/2013
Members	\$30	\$40
Non-Members	\$55	\$75
Student Members	\$5	\$10

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.

I want to sign up for **Track 1:** **OR** **Track 2:**

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: Visa MasterCard American Express

Card #: _____ Expiration Date: _____

Cardholder Name (as it appears on card): _____

Cardholder Signature: _____

Payment may be mailed to: ISPE, Boston Area Chapter, 411 Waverley Oaks Road, Suite 331B, Waltham, MA 02452

Telephone: 781-647-ISPE (4773) ☒ Fax: 781-647-7222 ☒ Email: office@ispeboston.org

****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER April 11, 2013 ARE SUBJECT TO BILLING****

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DIRECTIONS:

From the East (Mass. Turnpike, including Logan Airport)

Take Mass. Turnpike (I-90) to Exit 11A (I-495). Proceed north to exit 25B (I-290), then west into Worcester. Take Exit 18 (Lincoln Sq., Rte. 9). Turn right at end of ramp, bear right (again) onto Concord St., and take an immediate right onto Prescott St. Take your first right onto Washburn Way and follow past the The WPI Life Sciences and Bioengineering Center (which will be the building on your left). Visitor parking is next to the building.

From the East (Rte. 9)

Follow Rte. 9 to Worcester. After crossing I-290, proceed down the hill to Lincoln Sq. Bear right onto Lincoln St., getting into the middle lane. At the next set of lights, turn left onto Concord St. and take an immediate right onto Prescott St. Take your first right onto Washburn Way and follow past the The WPI Life Sciences and Bioengineering Center (which will be the building on your left). Visitor parking is next to the building.

From the North

Take I-495 south to I-290. Follow directions from east (Mass. Turnpike). Take Exit 18 (Lincoln Sq., Rte. 9). Turn right at end of ramp, bear right (again) onto Concord St., and take an immediate right onto Prescott St. Take your first right onto Washburn Way and follow past the The WPI Life Sciences and Bioengineering Center (which will be the building on your left). Visitor parking is next to the building.

From the South and West

From western Massachusetts and Connecticut: Take I-84 to Mass. Turnpike (I-90). Take Exit 10 (Auburn) and proceed east on I-290 into Worcester. Take Exit 17 (Lincoln Sq., Rte. 9). Turn left at end of ramp and follow Rte. 9 west, down the hill, to Lincoln Sq. Bear right onto Lincoln St., getting into the middle lane. At the next set of lights, turn left onto Concord St. and take an immediate right onto Prescott St. Take your first right onto Washburn Way and follow past the The WPI Life Sciences and Bioengineering Center (which will be the building on your left). Visitor parking is next to the building.

Parking options include:

- Parking lot adjacent to the Parking Garage
- The WPI Visitors Lot is adjacent to Gateway Park I (60 Prescott Street).
- Park on far side of 50 and 60 Prescott Street, across from both Gateway Park buildings.
- Park on Washburn Street, the street that is behind the two Gateway Park buildings, and in front of the parking garage.
- **Please pay close attention to no parking signs to avoid being ticketed.**

For door to door directions, click [here](#).