

*ISPE Boston Area Chapter Presents:*  
**Tech Transfer: From Process Development to  
Product Manufacturing**

**Thursday, June 18, 2015**

5:30 pm to 8:00 pm

*Genzyme Center*

500 Kendall Street, Cambridge, MA 02142

**OR VIA SIMULCAST AT**

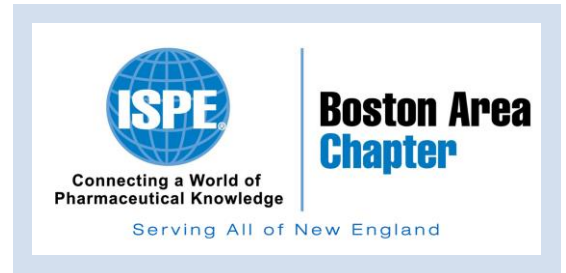
*Crowne Plaza Hotel Providence - Warwick*

801 Greenwich Street, Warwick, RI 02886

**AND in a NEW SIMULCAST LOCATION AT**

*WPI Biomanufacturing Education and Training Center at Gateway Park*

50 Prescott Street, Worcester, MA 01605



**EVENT INFORMATION:**

Attend the live program at Genzyme in Cambridge, MA or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI or at the WPI BETC at Gateway Park in Worcester, MA. The programs at all locations will feature a networking reception including appetizers.

**PROGRAM SUMMARY:**

The research, development and manufacturing of drug products present many challenges for engineers and scientists. The path from process development to product manufacturing involves a multitude of disciplines with specific expertise. Each stage has unique technical, economic, and regulatory requirements.

Over the years, companies have strategically focused their development efforts and manufacturing capabilities based on the costs and risks required to support multiple product groups and manufacturing operations. As internal resources become strained, or as the desire to explore new opportunities arise, companies may turn to contract development and manufacturing sites for external support as an alternative to in-house investment. Engineering, science, quality and regulatory teams are vital in facilitating the technology transfer of the product and managing the contracted site.

At the same time, regulatory agencies are taking a greater interest in the use of contract research organizations (CROs), contract manufacturing organizations (CMOs), and the companies that are utilizing them. Agencies have identified the transfer of the process between different sites as an opportunity to focus on quality by design (QbD) elements early in the process.

This educational event will involve several brief presentations about drug product manufacturing from process development stages to external manufacturing. Afterwards, there will be a moderated Q&A session where questions can be answered by our experts. The panelists represent varying disciplines in the industry. We'll hear about methodology for CMO selection, how to effectively partner with a CMO, and get tips from the CMO side on how to be a great sponsor company.

## **MODERATOR:**

### **Bhavi Mittal, PhD, Senior Scientist, Formulation Sciences, Millennium/Takeda Pharmaceuticals (Cambridge, MA)**

Bhavishya Mittal is a Senior Scientist in the Formulation Sciences department at Takeda Pharmaceuticals International Company based in Cambridge, MA. Bhavi has a PhD in Materials Engineering from the Pennsylvania State University and a BS in Chemical Engineering from Regional Engineering College, Jalandhar (India). Bhavi has 12 years of industrial experience in formulation and process development of various solid oral dosages of small therapeutic molecules (oncology, inflammation, and CNS indications) aimed for NDA and ANDA filings. He is the author/co-author of 1 patent application, 10 peer-reviewed manuscripts, and numerous conference papers and posters published/presented in various international journals and conferences. His research interests include formulation design, process engineering, scale-up and tech-transfer, and computational modeling of pharmaceutical unit operations for solid oral dosage manufacturing.

## **SPEAKERS:**

### **Claudia Buser, PhD, Director, Cell Banking Development, Genzyme (Framingham, MA)**

Claudia has been with Genzyme, now Sanofi, since 1995. She started as a process scientist, and has over 20 years of cell culture and process development experience. She has participated in the development and commercialization of several of Genzyme's recombinant therapeutic proteins produced in perfusion culture. Currently, her main responsibilities include leading a small group focused on cell banking development and late-stage development and tech transfer for a pipeline therapeutic. Her group is developing high density cell banks to support Genzyme's new continuous manufacturing platform. Her previous experience includes responsibility for production of GMP banks, and prior to that, late stage upstream development. Her responsibilities have included cell culture process development, scale-down and scale-up, technology transfer to manufacturing, and manufacturing support for commercial processes. Prior to joining Genzyme, Claudia worked at Wyeth Laboratories and also at Repligen Corporation. Claudia has a BS in Chemical Engineering and a PhD in Biochemical Engineering, both from MIT.

### **Gary Mills, Associate Director, Drug Product Development, Momenta Pharmaceuticals (Cambridge, MA)**

Over 27 years of experience in the design, development, technical transfer and commercialization of aseptic and purification processes associated with the production of biopharmaceuticals. To date have contributed to the successful commercialization of three biologics, two complex generics, one ultrasound imaging contrast agent and one reusable auto-injector device for prefilled syringes. Currently responsible for the oversight of parenteral drug product manufacturing at Momenta's contract manufacturing organizations, including management of technology transfer, scale-up, process optimization and trouble-shooting, and validation activities. Prior to joining Momenta, Gary worked at MassBiologics, TKT and Genzyme. Gary has a BS in Chemical Engineering from UMass Lowell and a MS in Engineering Management from Northeastern University.

### **Joe Cobb, CPIP, Director, Pharmaceutical Development, Metrics Contract Services/Mayne Pharma US (Greenville, NC)**

Joe has worked at Metrics for 13 years starting as a Pharmaceutical Development Scientist and has been responsible for the execution of dozens of contract service projects ranging from early phase, first-in-human trials all the way to commercial process validation. He has 22 years in the industry, serving in similar roles previously for DSM/Patheon and Geneva (Sandoz) Pharmaceuticals. He has expertise in most areas of solid oral dosage form manufacturing including standard tablet/capsule dosage forms and a variety of modified-release or bioavailability enhancement technologies. He is a graduate of The Ohio State University and is one of 149 Certified Pharmaceutical Industry Professionals world-wide as awarded by ISPE/PCC.

## **MEETING MANAGERS:**

**Howard Sneider, CRB Consulting Engineers**

**Jonathan Ly, Barry-Wehmiller Design Group**

**Norline Crossdale-Walker, Genzyme**

**Zeke Johnston, AMAG Pharmaceuticals**

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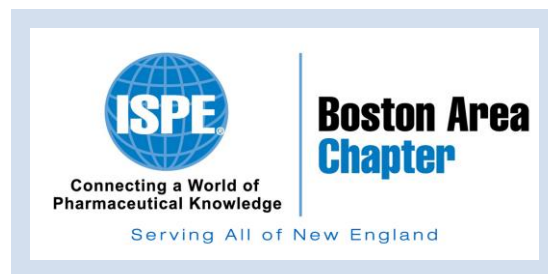
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**AND in a NEW SIMULCAST LOCATION AT**

*WPI BETC at Gateway Park,*

50 Prescott Street, Worcester, MA 01605



**PROGRAM SCHEDULE:**

5:30 – 6:30 PM Registration and Networking Reception

6:30 – 8:30 PM Presentations

**REGISTRATION FEES:**

	<b>Registration by 6/11/2015</b>	<b>Registration After 6/11/2015</b>
<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Young Professional Members	\$20	\$30
<input type="checkbox"/> Nonmembers **	\$95	\$115
<input type="checkbox"/> Student Members	FREE	FREE
<input type="checkbox"/> Simulcast in Warwick, RI	FREE	FREE
<input type="checkbox"/> Simulcast in Worcester, MA	FREE	FREE

\*\* Attendees may only attend one program as a nonmember.

**REGISTRATION IS NOW OPEN ONLINE!**

Don't waste time filling in the form! Register online at [www.ISPEBoston.org/Events](http://www.ISPEBoston.org/Events).

Pay by credit card OR check.

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, 465 Waverley Oaks Road, Suite 421, Waltham, MA 02452

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

**\*\*PLEASE NOTE: CANCELLATIONS RECEIVED AFTER June 11 ARE SUBJECT TO BILLING\*\***

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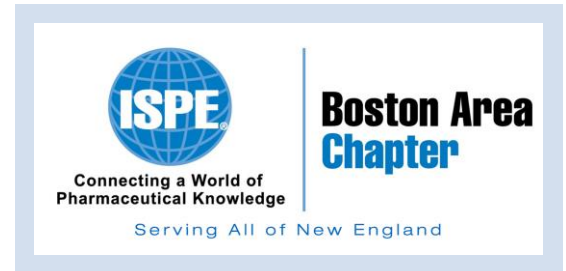
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**DIRECTIONS:**

**From the Expressway North**

Take exit 26 towards MA-3 North towards MA-28 North/Storrow Drive/North Station. Keep right at the fork and follow signs for MA-28 North/Leverett Circle/North Station. Keep left at the fork and follow signs for MA-28 North/Monsignor O'Brien Highway. Continue straight and turn left onto Nashua Street. Take the 1st right onto MA-28 North/Monsignor O'Brien Highway. Turn left onto Edwin H. Land Blvd. Turn right onto Binney Street. Take left onto Third Street. Take the 3rd left onto Kendall Street. The parking garage is on your right.

**From the Expressway South**

Take exit 26 towards Storrow Drive. Keep in the left lane and follow signs for MA-28 North. Turn slight right onto MA-28 North/Monsignor O'Brien Highway. Turn left onto Edwin H. Land Blvd. Turn right onto Binney Street. Take left onto Third Street. Take the 3rd left onto Kendall Street. The parking garage is on your right.

**From the Massachusetts Turnpike (I-90 Eastbound)**

Take the Mass Turnpike East. Take Exit 18 (Allston/Cambridge). Follow signs toward Cambridge/Somerville. The Doubletree Guest Suites Hotel will be on your right. At the traffic light, continue straight, crossing the river. Take the 1st right onto Memorial Drive. Continue onto Edwin H. Land Boulevard. Turn left onto Binney Street. Take left onto Third Street. Take the 3rd left onto Kendall Street. The parking garage is on your right.

**From the "T"**

Take the Red Line to the Kendall Square stop. When you exit the station, you will be on Main Street. Walk East - towards Boston - and you will see a traffic light at the corner of Broadway and Third Street. Cross at the intersection and walk down Third Street. Take your first right onto Kendall Street. Genzyme Center is the first building on the left.

**SIMULCAST LOCATIONS:**

***Crowne Plaza Hotel Providence - Warwick***

801 Greenwich Street, Warwick, RI 02886

**To the Crowne Plaza Hotel Providence – Warwick, RI:**

<http://www.crownehotelwarwick.com/index.cfm/page/Contact-Us/pid/10269>

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

## ***WPI BETC at Gateway Park, 50 Prescott Street, Worcester, MA 01605***

### **To the WPI BETC at Gateway Park – Worcester, MA:**

#### **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 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](#).**