

*ISPE Boston Area Chapter Presents:*  
**Dancing Through Traffic:  
Facility Expansions in Operating Plants**

**Thursday, February 18, 2016**

5:30 pm to 9:00 pm

***Genzyme Center***

500 Kendall Street, Cambridge, MA 02142

**OR VIA SIMULCAST AT**

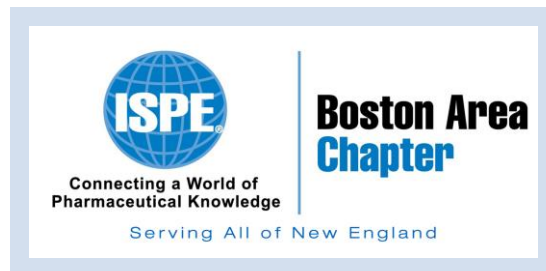
***Crowne Plaza Hotel Providence - Warwick***

801 Greenwich Street, Warwick, RI 02886

**AND**

***WPI Biomanufacturing Education and  
Training Center at Gateway Park***

50 Prescott Street, Worcester, MA 01605



THANK YOU TO OUR PROGRAM SPONSOR



**EVENT INFORMATION:**

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

**PROGRAM SUMMARY:**

When companies determine their current GMP facilities cannot support current or future manufacturing requirements, they need to choose whether to renovate, expand, or relocate. Often the decision to retrofit and remediate is the least costly option but most challenging because it must occur in tight quarters with minimal disruption to ongoing processes. Successful execution of these projects require a different approach than the fundamental or classic approach to planning and design. Our speakers will provide direction and strategies that are well-suited to these types of projects.

Specifically, this evening's program will:

- Methodically presents a different approach to planning and implementation to mitigate product risks and business vulnerability
- Addresses these key Owner concerns: Limiting production interruptions, developing a high-confidence schedule, proving no adverse effects to process under modification, to product concurrently in-process or to regulatory filings
- Discusses considerations in all phases of the project lifecycle: Design, Planning, Execution, Return-to-Service
- Suggests a dramatic shift in the approach to the planning and implementation of retrofit or remediation projects
- Illustrates with case studies and leaves attendees with actionable information

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## **WHO SHOULD ATTEND:**

This presentation is intended for industry professionals seeking to gain a better understanding of the challenges of performing facility projects in operating GMP facilities.

## **SPEAKERS:**

### **Richard Kotosky, PE, CPIP, Senior Project Manager, Hargrove Life Sciences**

Rick is a Senior Project Manager with Hargrove Life Sciences New England Operations with over thirty years of experience. He has held design engineering and project management positions with consulting A/E firms and has also worked directly for manufacturers of biologics, MAbs, vaccines, and medical devices. His operational experience includes roles from Senior Process Engineer to Senior Director of Facilities Operations and he has successfully managed retrofit projects and coordinated full plant maintenance and repair shutdowns in FDA licensed facilities that date back to the early 1900s. Rick is an active member of ISPE and earned his Certified Pharmaceutical Industry Professional™ credential in 2013. He holds a BS in Chemical Engineering from MIT and an MBA from Boston University.

### **John Spohn, CPIP, Senior Project Manager, Hargrove Life Sciences**

John is a Senior Project Manager with Hargrove Life Sciences New England Operations. John has provided owner's representative services and managed mission-critical projects in biotechnology, pharmaceutical and other industries. He has over thirty years' experience in the design and implementation of automated processes, systems and equipment. John is an active member of the ISPE and earned its Certified Pharmaceutical Industry Professional™ credential in 2011. He serves on the Boston Area Chapter Board of Directors and Educational Program Committee, managing educational presentations and authoring articles and presentations on topics of interest to the Pharmaceutical Engineering community. John is co-author of the Pharmaceutical Engineering 2013 Article of the Year: "Automating a Manual Cleaning Program In a Multi-Product Biopharmaceutical Manufacturing Operation". He holds a BS in Mechanical Engineering from Rensselaer Polytechnic Institute.

## **MEETING MANAGERS:**

**Norline Crossdale-Walker**, Genzyme

**Joseph Kifer**, RDK Engineers

**Heather Longden**, Waters

**David Novak**, OSDV Engineers, Inc.

**Rose Mary Su**, Acentech

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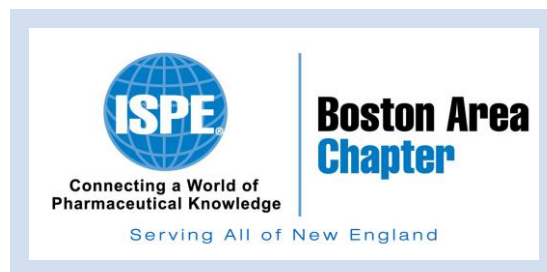
801 Greenwich Street, Warwick, RI 02886

**AND**

*WPI Biomanufacturing Education and Training Center 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

8:30 – 9:00 PM Additional Q&A Session

**REGISTRATION FEES:**

	<b>Registration by 2/11/2016</b>	<b>Registration After 2/11/2016</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 FEBRUARY 11 ARE SUBJECT TO BILLING\*\***

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50 Prescott Street, Worcester, MA 01605

**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**

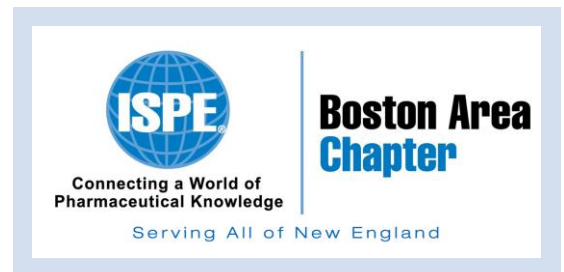
Take exit 26 towards Storrow Drive. Keep in the left lane and follow signs for MA-28 North. Turn slight right onto MA-28 North/Monsignor O'Brien Highway. Turn left onto Edwin H. Land Blvd. Turn right onto Binney Street. Take left onto Third Street. Take the 3rd left onto Kendall Street. The parking garage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