

ISPE Boston Area Chapter Presents:
**Myth Busting Biopharm Facility Designs
through Leading Edge Concepts**

Thursday, February 19, 2015

5:30 pm to 8:30 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 Center 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 three locations will include a networking reception including appetizers.

PROGRAM SUMMARY:

The emerging trends in our highly regulated industry require a unique approach and broad experience base to optimize facility designs and implement process improvements in a validated environment. This event brings three industry experts together to provide diverse perspectives on trends, techniques and strategies to implement world-class facility operations. There is a revolution within the Biotech and Pharmaceutical Industries where sharing best practices will enhance standards to address emerging issues such as process complexity, adoption of new technologies, and contamination risks. This collaborative event brings these unique perspectives together, covering:

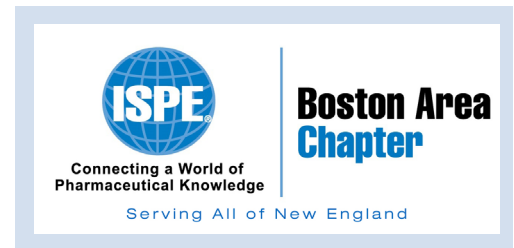
Facilities Optimization Design Perspectives

The first presentation will illustrate areas where facility design is impacted by the number of products in the pipeline, operational ease, operating costs, and the impact of yield changes. Facility Design Optimization is often overlooked or not fully addressed when developing a facility for a specific process. Designing an optimal facility requires the input from all stakeholders and incorporating critical input ensuring compliance and consideration for process, risk(s), compliance and operations into account.

Biotech Facility Best Practices

The second presentation focuses on Biotech manufacturing facilities with complex and technical cleaning requirements. Real World examples of FDA requirements, Quality Practices and Consultant Advice in the Biopharm industry that have contributed to high costs, poor facility hygiene and increased operator and building hazards. There is Best Practice that keeps patients and operators safe and complies with cGMPs will be shared. These Best Practices will be covered in this presentation, where common myths will be busted.

Continued on next page ...



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PROGRAM SUMMARY CONT.

Facility Optimization Considerations

The closing presentation will provide broad range of consideration exploring Facilities Optimization from the Facilities Management and Facilities Engineering viewpoint. We hear a lot about design, construction and optimization of layout, utilities, capacity and processing areas of new facilities. This presentation looks at a wide range of optimization considerations, including; maintenance programs, calibration and maintenance intervals, capital budgets and resources, facility and utility robustness, process optimization, and evaluations techniques for these categories. Considerations to maximize capital budgets and thoughts on optimal facilities team composition to successfully operate these complex facilities – what? This sentence is missing a closing.

Please join these industry experts and our distinguished panel to learn more about these topics and participate in a Q&A session at this ISPE Boston educational event.

SPEAKERS:

William Jacobsen, Chief Technology Officer, Dovetail Integrated Systems

Mr. Jacobsen has responsibility for leading initiatives focused on optimization and standardization of manufacturing operations. Mr. Jacobsen has extensive experience in biotechnology process development, manufacturing and operations and is considered a subject matter expert for single use systems. He has played key roles in the design, start-up, validation and operation of cell culture facilities at numerous Boston based Biologics companies. These facilities ranged from pilot to full-scale manufacturing. As a consultant, Mr. Jacobsen led the \$20M facility expansion at a newly formed CMO based on single use systems. Mr. Jacobsen received his BS in in-vitro cell Biology from the State University of New York at Plattsburgh.

Doyle Johnson, Life Sciences Industry Leader, Hargrove Life Sciences, LLC

Doyle has over thirty years of domestic and international experience in in the chemical, pharmaceutical and biotech industries. His expertise and knowledge includes hands-on operations and project management, technical and business management, process engineering, customer relations and regulatory requirements. Experiences include managing projects up to \$120MM total installed cost. Doyle has experience from the owner's side (Genzyme, MassBiologics) as well as the contractor's side (CDI/Herzog-Hart, and Hargrove Life Sciences, LLC). As testament to his leadership and expertise, Doyle served on the Board of Directors for the International Society for Pharmaceutical Engineering (ISPE) and the Engineering and Construction Contracting Association (ECC). Doyle has particular skills in Site Remediation, having been part of the Site Leadership Team at Genzyme during their FDA Consent Decree period. He has managed the operation of two large facilities in Boston – the MassBiologics Laboratories and Genzyme Framingham.

Mike St. Louis, Vice President of Operations, CPS Group

Mike St. Louis has 22 years of experience in construction and operation of high technology facilities serving the Semiconductor, Pharmaceutical and Biotechnology industry. He previously worked at Olympus Biotech (formerly Stryker) and prior to that Project Manager for Kinetic Systems, Inc. In that time his experience included roles as a Project Engineer, Project Manager, Manager of Capital Projects, Facilities Engineering Manager and Director of Plant Services, participating in the design, construction, commissioning, qualification and operation of process utility systems. Mr. St. Louis holds a BS degree in Construction Management from Boise State University, and Associate degrees in Architectural Engineering and Building Technology from Vermont Technical College. He has been a long time ISPE member.

MEETING MANAGERS:

Maurizio Cattaneo, BioVolutions

Terry Butler, Hallam-ICS

Nonjaros Chomcharn, Lyne Labs

Sean Brown, Barry Wehmiller

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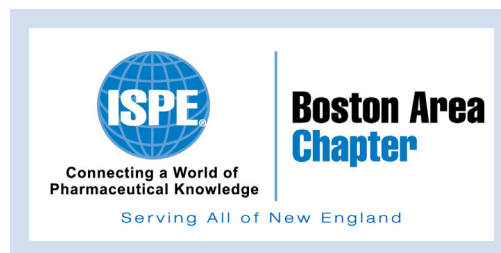
Genzyme Center, 500 Kendall St., Cambridge, MA 02142

OR VIA SIMULCAST AT

Crowne Plaza Hotel Providence - Warwick, 801 Greenwich Street, Warwick, RI 02886

AND in a NEW SIMULCAST LOCATION AT

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



PROGRAM SCHEDULE: *Applies to all sites*

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

6:30 – 8:30 PM Presentations

REGISTRATION FEES:

	Registration by 2/12/2015	Registration After 2/12/2015
<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Young Professional Members	\$20	\$30
<input type="checkbox"/> Nonmembers **	\$95	\$115
<input type="checkbox"/> Students 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.

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, 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 February 12 ARE SUBJECT TO BILLING****

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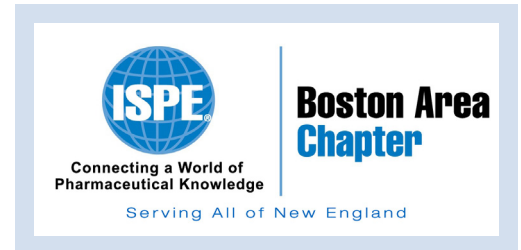
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500 Kendall St., Cambridge, MA 02142



To Genzyme Center – Cambridge, MA:

From the Expressway North/South

Take the exit for Storrow Drive. Follow Storrow Drive to the Kendall Square/Government Center exit, and follow the signs for Kendall Square, which will send you across the Longfellow Bridge and into Cambridge. After crossing the river, take a right at the first set of lights onto Third Street. Turn right 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 take a right onto Storrow Drive. Do not cross the river. Take the Kendall Square/Government Center exit off Storrow Drive. Follow the signs for Kendall Square, bearing left around the rotary and across the Longfellow Bridge into Cambridge. After crossing the river, take a right at the first set of lights onto Third Street. Turn right 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:

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

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

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](#).