

ISPE Boston Area Chapter Presents:
**Design Review and Optimization of
CIP and SIP Processes**

Thursday, January 19, 2017
5:30 pm to 9:00 pm

Framingham State University

D. Justin McCarthy Campus Center – Forum Auditorium
100 State Street, Framingham, MA 01701



THANK YOU TO OUR
PROGRAM SPONSOR



EVENT INFORMATION:

You are invited to attend a live program on optimized process systems design strategies and microbial preventative measures. The program will be held at Framingham State University's D. Justin McCarthy Campus Center – Forum Auditorium in Framingham, MA (venue kindly provided by the Framingham State University, Biotechnology Program). The event will feature a networking reception with appetizers and refreshments, and a live Q&A session after the presentation. Register now for this great program!

PROGRAM SUMMARY:

Current Best Practices for Biopharma Process Systems Design Strategies for Optimized CIP Performance (John Hyde). John will present a number of recent design reviews providing case studies to illustrate the concepts.

Prevention of microbial ingress within biologics process (Joe Povenski). Prevention of microbial ingress within any biologics process offers numerous challenges. If any measure or control is ignored or discounted, the frequency of a contamination event can increase exponentially. Any risk to the process should be acknowledged and remediated when possible, even when considered quantitatively low. Evaluating sterilization methods in response to such an event is critical and a key to the overall success of the investigation. The goal of the presentation is to review sterilization principles and how to identify sterilization deficiencies within the overall investigation roadmap.

WHO SHOULD ATTEND?

Validation and Facility Engineers, Quality Assurance Professionals, QC Microbiology and Contamination Control Professionals, Capital Projects Managers, Manufacturing Science and Technology Engineers.

SPEAKERS:

John Hyde, Chairman and Founder, Hyde Engineering + Consulting, Inc.

John Hyde founded Hyde Engineering + Consulting, Inc. in 1993 and specializing in process engineering, process and equipment validation, and compliance consulting for biopharmaceutical and pharmaceutical manufacturers. Hyde Engineering + Consulting, Inc. have operations in the United States, Europe, Singapore and India. For nearly two years prior to the formation of Hyde Engineering + Consulting, Inc., John was Senior Project Engineer with Synergen, a biopharmaceutical research and manufacturing company located in Boulder, CO.

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His work at Synergen included design, start-up and validation of key process systems and the overall responsibility for the cleaning validation programs for the firm's large scale and clinical manufacturing facilities. From 1982 to 1992, John was Manager, Process Design with Seiberling Associates, Inc., an engineering firm specializing in the design and start-up of biopharmaceutical, food and beverage process systems and the application of CIP technology.

Joe Povenski, Process Specialist, CRB

With 18 years of experience from the owner's side ranging from process development to licensed commercial manufacturing, Joe hopes to give an end user, customer focused perspective when response to a microbial contamination event is warranted. Having facilitated several microbial ingress investigations in the past, those experiences have lead Joe to a comprehensive understanding of all aspects of critical process design and microbial preventative measures.

MEETING MANAGERS:

Robert Lucas, CAI

Gennady Malin, Sanofi Genzyme

Rami Mitri, Spectra Automation Ltd.

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PROGRAM SCHEDULE:

- 5:30 – 6:30 PM Registration and Networking Reception
- 6:30 – 8:30 PM Presentations
- 8:30 – 9:00 PM Q&A Session

REGISTRATION FEES:

	Registration by 1/12/2017	Registration After 1/12/2017
<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

** 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, 465 Waverley Oaks Road, Suite 421, Waltham, MA 02452
Telephone: 781-647-ISPE (4773) ☎ Fax: 781-647-7222 ☎ Email: office@ispeboston.org

****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER JANUARY 12TH ARE SUBJECT TO BILLING****

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DIRECTIONS:

Directions from the Massachusetts Turnpike (I-90):

Take Exit 12, follow Rt. 9 East two miles to the Edgell Rd.-Main St., Framingham Exit. Take your first right onto State Street and the Framingham State Campus. Follow a few blocks through campus. To reach the Maynard Road Lot, take your first right on Maynard; the lot is approximately one block down on your left. To reach the Maple Street lot, follow State Street a few blocks past the campus, to the intersection of State and Maple Streets.

From I-95 (Route 128):

Take Exit 25 to the Massachusetts Turnpike (I-90) West, and follow the directions above.

From Route 495:

Take Exit 22 to the Massachusetts Turnpike (I-90) East, and follow the directions above.

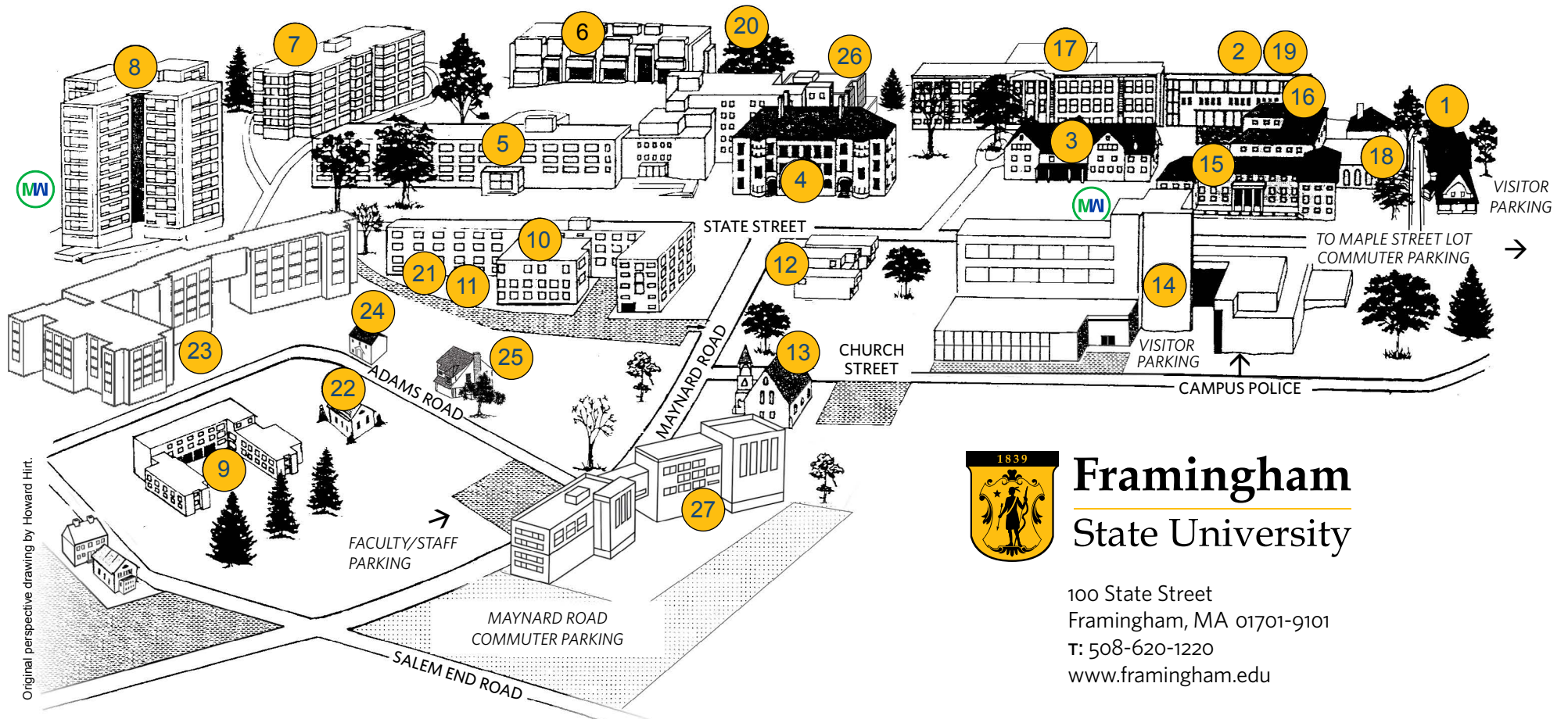
Parking

After 5pm, guests can park in most parking lots on campus. The Church Street Parking lot is closest to the building. Please see attached campus map. D. Justin McCarthy Center is number 14.

Public Transportation

FSU is located just a quick two-mile shuttle ride from the Framingham Commuter Rail Station on the MBTA's [Framingham/Worcester Line](#). You can find a complete schedule for the train at www.mbta.com. The University runs a shuttle to and from the train station with other stops at area retail stops like Shopper's World and the mall in Natick.

The [MetroWest Regional Transit Authority](#) also offers service from the train with their Route #7 and throughout the region with routes extending to Marlborough and Northborough, Milford, MassBay Community College, and the Woodland MBTA Station (Green Line - D) in Newton, as well as all along Rt. 9. Further details can be found at www.mwrta.com.



Original perspective drawing by Howard Hirt.



Framingham State University

100 State Street
Framingham, MA 01701-9101
T: 508-620-1220
www.framingham.edu

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|---|--|
| 1 - Admissions Welcome Center | 14 - D. Justin McCarthy Center |
| 2 - Bookstore | 15 - Horace Mann Hall |
| 3 - Crocker Hall | 16 - Peirce Hall |
| 4 - May Hall | 17 - Dwight Hall/Performing Arts Center |
| 5 - Hemenway Hall | 18 - CASA |
| 6 - Whittemore Library | 19 - Athletic/Recreation Center |
| 7 - Larned Hall | 20 - Arthur M. Doyle Information Technology Center |
| 8 - Corinne Hall Towers | 21 - Planetarium |
| 9 - Linsley Hall | 22 - Development & Alumni Relations |
| 10 - O'Connor Hall | 23 - North Hall |
| 11 - McAuliffe Center/
Challenger Center | 24 - Honors Program |
| 12 - Health & Wellness Ctr. - Foster Hall | 25 - Alumni House |
| 13 - Heineman Ecumenical & Cultural Center | 26 - Hemenway Laboratories |
| | 27 - West Hall (Under construction) |

Designates different MWRTA bus stops

DIRECTIONS TO OUR CAMPUS

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VISITOR PARKING

Limited visitor parking is available at the Admissions Welcome Center. Additional parking is available behind the McCarthy Center and in any of the Commuter Parking Lots.