

ISPE Boston Area Chapter Presents:

Shifting Paradigms in Pharmaceutical Water and Steam

Afternoon Session: The Current State of the Art in Pharmaceutical Water
Evening Session: Sampling of Pharmaceutical Water and Steam Systems

Thursday, February 16, 2017

3:00 pm to 8:30 pm

Biogen – Building 8 Auditorium

225 Binney Street, Cambridge, MA 02142

(Entrance at Building 9, 300 Binney Street)



ISPE®

**Boston Area
Chapter**

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EVENT INFORMATION:

You are invited to attend a live program presented by ISPE's Critical Utility Community of Practice on the Critical Utilities of Water and Steam Systems. The program will be held at Biogen in Cambridge (venue kindly provided by Biogen). The event will feature an afternoon educational session, networking reception with appetizers and refreshments, followed by an evening presentation. You are invited to attend either or both of the sessions for one low price. Register now for this great program!

PROGRAM SUMMARY:

Afternoon Session: The Current State of the Art in Pharmaceutical Water Systems

This session focuses on two important areas in Pharmaceutical Water: changes to USP <1231> and the evolution of rapid microbiological detection techniques and their impact on the biopharm industry.

The US Pharmacopoeia recently updated its non-binding guidance <1231> for the pharmaceutical industry. This session reviews the changes and updates to this important USP guidance document. Since USP <1231> is a living document, there will also be discussions about future revisions to this document, including some additional elemental monitoring requirements.

Recently, there have been advances in rapidly detecting bacteria present in pure water systems. These technological advances could have a widespread and positive impact in the biopharm industry as detection times change from 3 days to a few minutes. But technologies and detection limits vary and implementation of this new technology may pose challenges. Come to this session for an overview of the technologies in use, how they work, and learn about implementing a rapid microbiological detection system in a regulated environment.

PRESENTED BY:

Brian Hagopian, CPIP, Clear Water Consulting, Inc.

Joe Manfredi, GMP Systems, Inc.

*See biographies below

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Evening Session: Sampling of Pharmaceutical Water and Steam Systems

Sampling of compendial water and steam systems is required to demonstrate compliance with established process parameters and specifications. When any step of the sampling process isn't done properly, errors may be introduced and misrepresentative data can cost companies thousands if not millions of dollars by creating costly and unnecessary investigations and corrective actions. Sampling is an involved and complicated process and there is very little guidance on sampling – until now. ISPE has recently published *The ISPE Good Practice Guide: Sampling for Pharmaceutical Water, Steam, and Process Gases*, the first definitive guide to sampling. The guide provides expert guidance on all aspects of sampling. Attend this session to learn from contributing authors of the guide, who will highlight some of the content of the Sampling Guide. The information contained in this session, coupled with the Sampling Guide itself will become an indispensable tool to all users and custodians of water, steam, and process gas systems.

PRESENTED BY:

Joe Manfredi, GMP Systems, Inc.

Brian Pochini, CPIP, Sanofi Genzyme

*See biographies below

WHO SHOULD ATTEND?

This session will provide valuable information to engineering, design, facilities, manufacturing, quality, validation, and regulatory functions as well as anyone who wants to learn more about water and steam systems.

SPEAKER AND MODERATOR:

Brian Hagopian, CPIP, Clear Water Consulting, Inc.

Brian is a degreed chemist from Colgate University and is the President of Clear Water Consulting, Inc. Brian brings over 35 years of experience as a high purity water subject matter expert, consultant, trainer, educator, and expert troubleshooter. Brian is an instructor at Worcester Polytechnic Institute's Biomanufacturing Education and Training Center and is a Massachusetts certified instructor offering courses for industrial wastewater operators.

Brian has been an ISPE member since 1992 and has been an integral part of the growth of the Boston Area Chapter. In 2015, Brian became one of six people to have received the Hank Moes Lifetime Achievement Award for significant contributions to the Boston Area Chapter and the life sciences industry. Brian currently leads the Boston Area Chapter's Student Development Committee where student membership has grown five-fold over the past several years. Brian has been a member of the ISPE Critical Utilities COP Steering Committee for the past four years and has just finished leading a team of over 20 industry experts in publishing the ISPE Good Practice Guide on Sampling of Pharmaceutical Water, Steam, and Process Gases, which was released in December, 2016

SPEAKERS:

Joe Manfredi, GMP Systems, Inc.

Joe Manfredi is the President of GMP Systems where he has spent over 30 years designing systems, overseeing fabrication and installation, troubleshooting, training and providing consulting services for many of the world's major pharmaceutical manufacturers.

Joe was instrumental in establishing the Pharmaceutical Engineering Masters of Science Program at the New Jersey Institute of Technology, where he developed and taught many of the core graduate program courses and served as Chair of their Pharmaceutical Engineering Advisory Committee.

Joe is a graduate of Newark College of Engineering. His expertise includes all areas of liquid processing with a special emphasis on water and steam systems. Joe is a leading instructor of orbital welding technology for

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pharma and provides seminars in operator certification, orbital weld inspection and equipment calibration and service.

Joe was named ISPE Member of the Year in 1991 and Newark College of Engineering Distinguished Alumnus in 2004. Joe has been a long time member of the ISPE CU CoP steering committee and led the group of subject matter experts to produce the water chapter in the Sampling Guide

Brian Pochini, CPIP, Sanofi Genzyme

Brian is a principal Engineer working in Sanofi Specialty Care Operations Engineering. Brian attained his Bachelor's Degree in Chemical Engineering from Worcester Polytechnic Institute, his MBA from Bentley University, and attained his CPIP Credential from ISPE in 2012.

Brian has 20 years of practical experience within the biotechnology, membrane manufacturing and custom chemical industries. Brian's current responsibilities encompass many functions including HVAC, Critical Utilities, Process Engineering, Instrumentation and Controls, and Facility Design where he works with cross functional teams for multiple capital projects.

Brian is a former member of the ISPE C+Q Steering Committee and is currently the Chair of the ISPE Critical Utility COP Steering Committee. Brian led the team of experts in producing the steam chapter for the Sampling Guide.

MEETING MANAGERS:

Jim Taylor, Lean Biologix

Brian Hagopian, Clear Water Consulting, Inc.

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PROGRAM SCHEDULE:

Afternoon Registration and Networking Reception:	3:00 PM – 3:30 PM
Afternoon Presentation:	3:30 PM – 5:30 PM
Evening Session Registration:	5:30 PM – 6:00 PM
Evening Networking Reception:	5:30 PM – 6:30 PM
Evening Presentation:	6:30 PM – 8:30 PM

REGISTRATION FEES:

	Registration by 2/9/2017	Registration After 2/9/2017
<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

I Plan to Attend: Afternoon Presentation Networking Reception Evening Presentation

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 FEBRUARY 9TH ARE SUBJECT TO BILLING****

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DIRECTIONS:

Click Here for Door to Door Driving Directions: [DIRECTIONS](#)

From MBTA (The "T"):

Take the Red Line "T" to Kendall Square/MIT stop. Walk straight up the stairs. Turn right on Main. Walk to next light, then turn right on Ames, follow to Broadway, cross Broadway and turn left. Biogen will be on your right. Look for the Parking Garage between 2 Biogen buildings and enter the last Building on the left across from the Parking Garage

From North or South:

Rte. 93 to the Storrow Drive Exit. Follow signs for Storrow Drive. Take Storrow Drive to exit marked Mass Ave, Cambridge. Cross the Mass Ave Bridge over Charles River. Turn right on Vassar Street, which turns into Binney Street. Cross Main Street and Broadway, Binney will bend to the right and you will see Building 8 on your right. After passing Building 8, turn right to enter the Parking Garage.

From Waltham & Route 2:

Rte. 2 to Memorial Drive eastbound. (You will pass Harvard University, The B.U. Bridge, The Mass Ave. Bridge and MIT.) After passing MIT, stay to the right, following signs toward Kendall Square (do not follow signs toward Boston). Take left at first set of lights (2nd Kendall Square sign) onto Binney Street. Pass Third Street and look for the Parking Garage on the left.

From Mass Ave:

Follow Mass Ave. onto Main Street. Turn left on Vassar Street, which turns into Binney Street. Cross Main Street and Broadway, Binney will bend to the right and you will see Building 8 and 9 on your right. After passing Building 9, take your second right to enter the Parking Garage.

From West & Mass Pike:

Take Mass Pike to Exit 18 (Cambridge/Allston/Brighton Exit). After toll, bear right (Cambridge/Somerville). Go straight across River Street Bridge. Turn right onto Memorial Drive eastbound. After passing MIT, stay to

the right following signs toward Kendall Square (do not follow signs toward Boston). Take left at first set of lights (2nd Kendall Square sign) onto Binney Street. Pass Third Street and look for the Parking Garage on the left.

PARKING: On street parking meters are free after 6PM.

The closest Parking Garage is between Biogen Buildings 6 and 8, but there are several other Parking Garages in the general vicinity of the facility.

