

# Utilities Not Included

**Thursday, October 19, 2017**

**5:30pm - 6:30pm – Networking Hour**

Egan Research Center, Room 306  
Northeastern University  
120 Forsyth St, Boston, MA 02115

**6:30pm - 9:00pm – High-Purity Water and HVAC Systems Workshop**

Egan Research Center, Room 440



Control of the manufacturing environment and utilities are critical elements of implementing a successful pharmaceutical manufacturing process. Engineers entering the pharmaceutical and biopharmaceutical industries can find excellent opportunities in the design and implementation of high-purity water and HVAC systems. Process engineers should also have a working knowledge of the utility systems which support their processes. This workshop will provide students and young professionals with a basic understanding of the terminology and industry jargon associated with high-purity water and HVAC systems, as well as the purpose and function of the system components.

**Registration Fee: Early Bird, ends 10/12/17**

Student: Free  
Member: \$50  
YP Member: \$20  
Nonmember: \$95

**Regular, starts 10/13/17**

Student: Free  
Member: \$60  
YP Member: \$30  
Nonmember: \$115

*Light dinner fare and appetizers will be served during the networking hour.*

Register Now online at: <http://www.ispeboston.org/events>

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**Speakers:**

**Jay Zaino** is the former president and co-founder of GxP Automation, LLC which was acquired by Albireo Energy in 2015. Currently, Mr. Zaino is an independent consultant to the local Life Science market. He has over 26 successful years in engineering, software development, and validation strategies for critical automation systems serving the Life Science Industry. Mr. Zaino is a Past President of the Boston Chapter of ISPE and currently serves on the Scholarship Committee. Mr. Zaino is an industry leader in implementing new facility integration technologies, automation initiatives, and validation strategies for the pharmaceutical, biotech, and medical device markets.

**Brian Hagopian, CPIP** received his degree in chemistry from Colgate University a long time ago and is currently the President of Clear Water Consulting, Inc. Brian has over 35 years of design, manufacturing and operational experience with water purification systems and is a subject matter expert, consultant, trainer, educator, and expert troubleshooter helping clients solve complex operational problems, assess risks, address compliance observations, and document activities. Brian is an instructor at Worcester Polytechnic Institute's Biomanufacturing Education and Training Center and is also certified by the Commonwealth of Massachusetts as an instructor offering courses for the training and licensing of industrial wastewater operators. Brian is a charter member and Past President of the Boston Area Chapter where he helped to build the foundation for the Boston Chapter's highly successful Product Show, which has won two International awards for "Best Special Event" at ISPE Annual Meetings. Brian ran point on the Product Show when it moved from Cambridge to Newton and was one of the people responsible for bringing the show to Gillette Stadium, where he ran the show for its first four years at Gillette. Brian is one of 150 people worldwide to have attained the Certified Pharmaceutical Industry Professional (CPIP) certification. Brian led several CPIP study groups that resulted in the Boston Chapter being home to about 50% of the world's CPIP's. Brian is one of only eight people to have received the prestigious Hank Moes Lifetime Achievement Award for significant contributions to the Boston Area Chapter and the Life Sciences industry. Brian has led the Boston Chapter's Student Development Committee for the past six years and his efforts have brought growth and stability with student membership quadrupling and the number of student chapters doubling through these efforts. Brian has also been an active member of the ISPE International Critical Utilities Community of Practice Steering Committee where he recently led a team of subject matter experts in the publication of a long overdue benchmark document: The ISPE Good Practice Guide on Sampling of Critical Utilities, which was published in December 2016.

**Presentation Abstract:**

**HVAC Systems** One key of automation is understanding the process and understanding the cause and affect of our everyday actions. This presentation will review the basics of HVAC operation enabling attendees to understand the systems controlling the laboratory and production suite environments utilized for research and to manufacture product. This presentation is geared towards those with little to no facilities background or those in facilities who wish to review the very basic operation of HVAC systems serving critical environments. In addition, it will review the basics of the associated automation theory which allows the systems to operate and maintain personnel, equipment, and product requirements. Attendees will learn how their actions in one environment affects adjacent environments and what automation systems are in place in today's facilities to compensate for those actions to prevent personnel discomfort, ensure environmental safety, and maintain product requirements.

**High Purity Water Systems** Water is the most commonly used material in the manufacture and purification of many biotech and pharmaceutical products as well as medical devices. Water is used as an ingredient, a solvent, a diluent, a cleaner, and for many other purposes. We will start by focusing on the contaminants and impurities present in the incoming water supply and then focus on what needs to be removed based on the intended use of the water. Attendees will learn about dozens of different water purification process and how they can be integrated to get the right water purity for the intended use. We will touch on different grades of water as identified by various pharmacopoeias and consensus standards (ASTM, CAP/CLSI, pharmaceutical, and microelectronics grades). Attendees will receive a broad overview of why different grades of water purity exist and, as time permits, we'll spend time focusing on three important topics: reverse osmosis, deionization, and bacteria.