

ISPE Boston Area Chapter Presents:

# Automation – The Real Story Behind the Curtain

**Thursday, January 19, 2012**

**Biogen Idec**

14 Cambridge Center, Cambridge, MA 02142

(Building 6 Auditorium)

**PROGRAM:** There has been much interest in the black box of automation. This program will give insight to the basics of automation found in the pharmaceutical industry, and the challenges that we face making the black box operate. Since critical automation of a pharmaceutical facility involves both HVAC and process control, the program will provide insight into both. Attendees will gain a basic understanding of HVAC theory of operation as well as a basic understanding of efficient design of process automation systems, allowing them to appreciate and understand what it takes from all team members to provide automation systems that will produce quality and consistent product research and production.

**PRESENTATION ONE:** 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 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 affect 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.

**SPEAKER ONE:** Jay Zaino is president and co-founder of **GxP Automation, LLC**. He has over 23 successful years in engineering, software development, and validation strategies for critical automation systems serving the Life Science Industry. Mr. Zaino is currently Vice President of the Boston Chapter of ISPE and serves on the Educational Programs 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.

**PRESENTATION TWO:** Process automation should be straight forward. Process Engineering determines what needs to be done, and Quality makes sure that what we do is compliant - but expectations for automation continue to evolve and there is no magic. This presentation discusses core functional requirements for control systems and ways to achieve a successful implementation. We'll look at modern pharmaceutical software architectures and at some of the architectural decisions that need to be made for each project. The importance of clearly communicating and clarifying requirements will be discussed, along with specific ways to manage and improve the detailed requirements definition process. Finally, rapidly-evolving technologies from smart I/O to server virtualization will be considered, while noting that adding new layers of complexity doesn't change the need for a clear overall architecture built with solid reusable components.

**SPEAKER TWO:** Doug Brenner is the Information and Technology Manager at **Superior Controls Inc.**, where he has developed and maintained validated monitoring, processing, batching, data collection, and reporting systems for a broad range of Pharmaceutical customers. Doug's 30-some years of experience includes Information Systems management, IS consulting, Production Control, Materials Management, and teaching. He has a B.A. in Math and Economics and an M.S. in Industrial Engineering from the University of Arizona.

## **MEETING MANAGER:**

Jack Greene, Genzyme Corp



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5:30 – 6:20 PM      General Registration and Networking  
Reception

6:20 – 6:30 PM      Welcome and Program Introduction

6:30 – 8:30 PM      Program



**REGISTRATION FEES:**      Registration by 1/12/2012      After 1/12/2012

<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Non-members	\$95	\$115
<input type="checkbox"/> Students	\$5	\$10

**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): \_\_\_\_\_

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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](mailto:office@ispeboston.org)

**\*\*PLEASE NOTE: CANCELLATIONS RECEIVED AFTER January 12th ARE SUBJECT TO BILLING\*\***

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**DIRECTIONS (click here):**

[http://maps.google.com/maps?f=q&source=s\\_q&hl=en&geocode=&q=14+Cambridge+Center,+Cambridge,+Massachusetts+02142&ll=42.2855,-71.4149&sspn=0.010953,0.019076&ie=UTF8&hq=&hnear=10+Cambridge+Center,+Cambridge,+Middlesex,+Massachusetts+02142&z=16](http://maps.google.com/maps?f=q&source=s_q&hl=en&geocode=&q=14+Cambridge+Center,+Cambridge,+Massachusetts+02142&ll=42.2855,-71.4149&sspn=0.010953,0.019076&ie=UTF8&hq=&hnear=10+Cambridge+Center,+Cambridge,+Middlesex,+Massachusetts+02142&z=16)

**OR**

**From MBTA (The "T"):**

Take the Red Line "T" to Kendall Square/MIT stop. Walk straight up the stairs.

**From North or South:**

Rte. 93 to the Storrow Drive Exit. Follow signs for Storrow Drive. Take Storrow Drive to Exit marked Kendall Square. Go across Longfellow Bridge over Charles River. Once you cross the Charles River, the road turns into Broadway.

**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. Take left at first set of lights (2nd Kendall Square sign) onto Binney Street. Take left at 2nd light onto Third Street. Proceed to end and turn right onto Broadway.

**From Mass Ave:**

Follow Mass Ave. onto Main Street. Take left onto Ames Street at Legal Seafood.

**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. Take left at first set of lights (2nd Kendall Square sign) onto Binney Street. Take left at 2nd light onto Third Street. Proceed to end and turn right onto driveway.

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

The closest Parking Garage, "Central Parking System," is at 4 Cambridge Center where parking is \$18 for up to three hours and \$24 for over three hours.

