

ISPE Boston Area Chapter Presents:
Our Process Is Working, Right?:
How do you really know? And can you know “in the moment”?

Thursday, June 20, 2013

5:30 pm to 8:30 pm

Tufts Gordon Institute

200 Boston Ave, Suite 2400

Medford, MA 02154



PROGRAM SUMMARY:

Come join the Boston Area Chapter for a dual track educational program focused specifically on Validation, defined as “the process of using objective evidence to establish that a process consistently produces a product or result meeting a predetermined specification.” Validation is such a broad topic that we can’t possibly cover everything with one program – so we’ve split the program into two concurrent tracks, one introductory and one advanced to best meet the varied needs of our membership. The **introductory track consists of two presentations** focused on providing attendees with the basics of validation along with why validation is required from an agency, process, and product lifecycle perspective. The **advanced track** takes a detailed look at validation beginning with a summary of industry and FDA contributions to the FDA Process Validation Guide. Two presentations will then focus on the emerging field of Continuous Process Verification (CPV) describing both a theoretical and actual case study detailing how CPV was implemented by a local life sciences company. The Tufts Gordon Institute in Medford has generously offered their facilities to host this program.

INTRODUCTORY TRACK:

This program begins with an introduction to the key regulatory agencies and their expectations with a practical discussion of product lifecycle implications. Next, the program shifts focus to provide attendees with an overview of validation basics and the key tenets behind validated processes and products. Attendees will come away with an understanding of the mindset behind and importance of integrating the process behind the product.

SPEAKERS:

Rich Yeaton is President of East Coast Validation Services, LLC in Derry, NH, and has over twenty years experience working in FDA regulated industries. He was initially introduced to GMP operations on the Devices side as a Development Engineer in DuPont’s Medical Products division, where he developed and improved new process equipment, and then was told to validate what he had designed.

He moved on to help start Phoenix Imperative, an Engineering and Validation consulting company serving the BioPharm industry. A key achievement with Phoenix was leading validation teams to assist MedImmune to obtain its first two commercial licenses. He has since worked with small startup companies and larger operating companies such as Shire, Merck, Genzyme, Wyeth and Lonza. He has in-depth experience with facility shutdowns and startups. He recently assisted Avecia Biologics, a microbial fermentation Contract Manufacturer, to successfully prepare for their first Pre Approval Inspection. He is currently working with a GMP Operating company to manage Process, Cleaning and Equipment validation efforts for a new combination product under development. He is a member of ISPE, PDA and AAMI and has degrees in Electrical Engineering and Mechanical Engineering from Lehigh University.

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INTRODUCTORY TRACK SPEAKERS Continued:

Jack Campion, PE, has held positions in process design, design-build project management, validation, and validation management for twenty-four years. He led the commissioning, qualification and process validation program for MassBiologics' 100,000 square foot cell culture and aseptic fill-finish facility in Mattapan. In this role, Jack applied the *ISPE Baseline® Guide Volume 5: Commissioning and Qualification*, saving countless labor hours and weeks of schedule through careful system definition and elimination of redundant testing. Jack was also a member of the design team and was responsible for system turnover and acceptance from the construction manager.

Jack holds a BA in chemistry from the College of the Holy Cross and an MS in Chemical Engineering from Tufts University. He is a registered Professional Engineer in Massachusetts. Jack is currently Manager of Project Controls for capital projects at Genzyme's Allston Landing Facility. He is a former Treasurer and current Member of the Board of Directors of the ISPE Boston Area Chapter.

ADVANCED TRACK:

This program takes a deep dive into the practical aspects of Process Validation. ISPE has solicited input from the industry as well as the FDA, and has developed an impressive stable of best practices in Process Validation. Our first presentation reviews the content of these reference materials. The second presentation focuses on the emerging field of Continuous Process Verification (CPV), which is considered the Holy Grail by both the FDA and the industry. Selection of critical process parameters to monitor, analyze data, and respond to process variability will be discussed first as part of a theoretical case study and then as applied in a real world example currently in use. Biogen Idec has developed a quantitative method for chromatogram review/evaluation. Multivariate analyses of the discrete parameters have been applied for evaluation and scale-down model verification. The author shares the journey of electronic chromatogram evaluation including the use of such methodology to identify the root cause for a product quality shift.

SPEAKERS:

Peter Levy has been involved in process development for the BioPharmaceutical and related industries for over 30 years. He began providing consulting services to the Pharmaceutical Industry in the areas of Process Development, Manufacturing, Technical Transfer, and Process Validation in 2007. He received his B.S. degree in Chemistry from Tufts University and M.S. degree in Chemical Engineering from Massachusetts Institute of Technology.

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ADVANCED TRACK SPEAKERS Continued:

Past employers include Biogen, Inc (Director Development Engineering & Validation), Millennium Pharmaceuticals (Director Biologics Process Development), Altus Pharmaceuticals (Director Process Development & Engineering), and

Amicon Division of WR Grace & Company (Manager, Process Filtration Applications). His focus has been on downstream processing of recombinant proteins with an emphasis on liquid-solid separations. His experience includes the development of processes and process equipment as well as technical transfer, start-up, and validation of clinical and commercial protein processes.

Mr. Levy is an active member of ISPE and participated in the ISPE PQLI PV Implementation Team that produced two discussion papers in 2012 and is presently working on 4 more discussion papers related to Process Validation.

Dr. Lilong Huang joined Biogen Idec in 2012 and is currently leading the global advanced process control (APC) initiative within the company. The mission of Biogen Idec’s APC initiative is to transform research, development, and manufacturing data into better process understanding and eventually into actions to achieve improved product quality. Dr. Huang has worked in Chemical, Vaccine, and Biological industries for the past 9 years. Prior to joining Biogen Idec, he worked at Bayer, Merck, and Genzyme. His expertise includes manufacturing support, new facility startup, facility utilization optimization, data analytics and process monitoring/control.

Dr. Huang graduate from Beijing University of Chemical Technology in 1996 with a Bachelor of Science degree and from Tsinghua University in 1999 with a Master of Science degree both in Chemical Engineering. He received a Ph.D. in Chemical Engineering from Lehigh University in Bethlehem, PA in 2004.

MEETING MANAGERS:

Brian Hagopian, CPIP, Clear Water Consulting

Armen Nahabedian, Pfizer

Chiderah Okoye, Venly, Inc.

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PROGRAM SCHEDULE:

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

6:30 – 8:30 PM Welcome & Program (Introductory and Advanced Tracks Run Concurrently)

REGISTRATION FEES:

Registration by 06/13/2013

After 06/13/2013

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

** Attendees may only attend one program as a non-member.

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.

I want to sign up for: Introductory Track 1: OR Advanced Track 2:

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 June 13th ARE SUBJECT TO BILLING****

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DIRECTIONS AND PARKING:

http://www.tufts.edu/home/visiting_directions/medford_somerville/

North

If you are approaching on Routes 1, 95, 128 or 93, take Route 93 south to Exit 32, Medford Square. From the exit ramp, take the first right off the traffic circle, which is Route 60 west. At the second set of lights, bear left on Main Street and take an immediate right on to Route 16 west.

Continue on Route 16 for approximately one and a quarter miles. An athletic field will appear on your right. Bear left through the next traffic circle and proceed up the hill on Powder House Boulevard. At the third traffic light turn left onto Packard Avenue. You are now on the Tufts campus.

Northwest

If you are approaching on Route 2 East, continue on Route 2, past the junction of Routes 2 and 95. If you are approaching on Route 3, take Route 95 south to Route 2 east (Exit 29A). At the junction of Routes 2 and 16, bear left through a full traffic light on Route 16 east.

Take Route 16 east through two full traffic lights. You will see blue signs on the right for Tufts University. Follow the blue signs and take a sharp right up the hill on Powder House Boulevard. At the third traffic light turn left onto Packard Avenue. You are now on the Tufts campus.

West or Southwest

If you are approaching on Routes 90 (Massachusetts Turnpike) or 95 take Route 95 north to Route 2 east (Exit 29A). At the junction of Routes 2 and 16, bear left through a full traffic light on Route 16 east and refer to directions in the preceding paragraph.

South or Boston

If you are coming from the south, take Route 3 north to Route 93 north. If coming from Boston, take Route 93 north. If coming from the airport, follow signs to Route 93 via the Sumner Tunnel. Take Route 93 north to Exit 31. Follow the exit ramp to Route 16 west and refer to directions in the first paragraph.

Subway or Boston

If you are coming by subway, or "T", take the Red Line to the Davis Square Station. Exit the Davis Square Station on the College Avenue side. You may take the #94 or #96 bus or walk 15 minutes along College Avenue to the Tufts campus. If you board the bus, ask the driver to stop across from the Memorial Steps at Tufts University, just before the intersection of College and Boston Avenues. If you walk, turn right out of the subway station and follow College Avenue around a traffic circle. The Tufts campus will be on your left.