

ISPE Boston Area Chapter and PDA New England Chapter Present: Process Validation Lifecycle Approach, A Return to Science

Wednesday, September 16, 2015

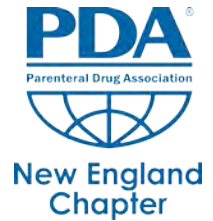
5:30 pm to 8:45 pm

Hilton

2 Forbes Road, Woburn, MA 01801



**Boston Area
Chapter**



EVENT INFO:

Do we have a blockbuster September program for you! For the first time ever, the ISPE Boston Area Chapter and the PDA New England Chapter have pooled resources to present an incredibly strong educational event to kick off the program year! The topic is Process Validation and we've secured two excellent speakers who will help us decode and understand guidance documents written by the FDA, ICH, PDA, ISPE, and other industry sources on the topic. Don't miss out on this one of a kind opportunity to meet, exchange ideas, and network with a much larger industry cross section than usually participates at these programs. Be sure to sign up now to secure your spot before the event sells out!

PROGRAM SUMMARY:

The expectations for process validation and process control have changed and are continuing to change – for the better. More and more global health authorities and regulators are communicating their expectations for risk and science based justification for process control and validation approaches. A true life cycle approach to process validation requires gathering useful, scientific information as process and control strategies are developed, thus saving time and resources during later qualification and validation stages. The key is better understanding of the process, its sources of variation and their control, and the correlation between validation studies, sampling plans, process performance, product quality, and continued process verification. These coordinated presentations will use recent global guidance, PDA Technical Report 60, ISPE white papers and other industry publications and examples to explore global expectations and approaches for process validation, the background leading to these expectations and approaches, as well as current trends and future direction.

SPEAKERS:



Rusty (Russell) Morrison is a Principal Consultant for CAI Consulting (a division of Commissioning Agents, Inc.), where he is responsible for the sales, marketing, and execution of qualification, process validation and technology transfer projects. He has directed multiple process validation efforts, including the complete process validation for the startup of a large cell culture monoclonal antibody manufacturing facility, and remedial process validation for a manufacturer of numerous small volume sterile parenteral products, including designing a continued process verification program. Mr. Morrison is a member of PDA and ISPE, and has served as a member of ISPE's Process Validation Implementation Team. In addition, he is a past president and board member of the PDA New England Chapter. Prior to CAI, Mr. Morrison held management and engineering positions with Protein Sciences Corporation, INNCOM International, and Sonalysts, Inc., and served as a submarine officer in the United States Navy. He has a BS in chemical engineering with honors from the University of Minnesota, an MBA in Information Systems from Rensselaer Polytechnic Institute, and has received ISPE's Certified Pharmaceutical Industry Professional (CPIP) credential.



Hal Baseman is Chief Operating Officer and a principal at ValSource LLC and ConcordiaValsource LLC. He has over 36 years of experience in pharmaceutical operations, validation, and regulatory compliance. He has held positions in executive management and technical operations at several drug manufacturing and consulting firms. He is the Chair of the Parenteral Drug Association (PDA) Board of Directors, former Chair of the PDA Science Advisory Board, former Co-Leader of the PDA Process Validation Interest Group, and co-leader of the PDA TR 60 task force, as well as a long-time member of the PDA Training Research Institute faculty. He is a frequent presenter on subjects related to Quality Risk Management, Validation, and Aseptic Processing. Hal holds an MBA in Management from LaSalle University and a B.S. in Biology from Ursinus College.

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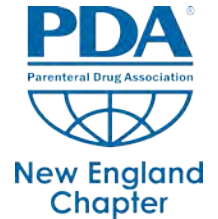
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WHO SHOULD ATTEND?

This educational session will be of great value to individuals responsible for the design, execution or evaluation of validation strategies and related activities. This includes directors, managers, supervisors and engineers in product development, validation, statistics, and process operations, as well as quality control, quality assurance and regulatory.

PROGRAM SCHEDULE:

5:30-6:30 PM – Registration, networking, light buffet

6:30-6:45 PM – Announcements

6:45-7:35 PM – Presentation #1, 10 minutes for Q+A

7:45-8:35 PM – Presentation #2, 10 minutes for Q+A

8:45 PM – Program adjourns, but networking and discussion will surely continue

DIRECTIONS: Hilton, Woburn, MA 01801

Traveling 93 North (From Boston/Logan Airport): Take Exit 36 (Montvale Ave.) Turn left off the exit. At second set of lights, turn right onto Washington St. Drive 1 mile on Washington St. to the second set of lights. Turn right onto Cedar St. Take immediate right onto Forbes Rd. Hotel is on left.

Traveling 93 South - From I-495 or Andover Area: Take Exit 37B for I-95 South. Stay in far right lane and take exit 36- Washington St./Woburn. Bear right off exit. At first light, turn right onto Washington St. At third set of lights, turn left on Cedar St. Take immediate right onto Forbes Road and Hilton is on the left.

Traveling 128/I-95 North (From Waltham Area/Mass Pike I-90) Take Exit 36 (Washington St.) Bear right off exit. At first light, turn right onto Washington St. At third set of lights, turn left on Cedar St. Take immediate right onto Forbes Road and Hilton is on the left.

Traveling 128/I-95 South (Peabody/Gloucester Area): Take Exit 36 (Washington St.) Bear right off the exit. At first light, turn right onto Washington St. At third set of lights, turn left on Cedar St. Take immediate right onto Forbes Road and Hilton is on the left.

PROGRAM MANAGERS:

Brian Hagopian, Clear Water Consulting, Inc.

Mallory Duquesne, Independent Consultant

Chris Ciampa, Thermo Fisher Scientific

Dan Mardirosian, Worcester Polytechnic Institute

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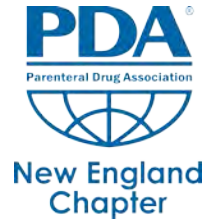
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REGISTRATION FEES:

**Registration by
11/Sep/2015**

**Registration After
11/Sep/2015**

<input type="checkbox"/> Members	\$55	\$85
<input type="checkbox"/> Young Professional Members	\$20	\$30
<input type="checkbox"/> Nonmembers	\$55	\$85
<input type="checkbox"/> Students Members	FREE	FREE

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 SEPT. 11, 2015 ARE SUBJECT TO BILLING****