

# *ISPE Boston Area Chapter and PDA New England Chapter Present:* **Validation: The Bridge Between Engineering & Quality Assurance**

**Wednesday, May 17, 2017**

5:30 pm to 9:00 pm

***Hilton Boston/Woburn***

2 Forbes Road, Woburn, MA 01801



**ISPE**®

**Boston Area  
Chapter**

Serving All of New England



**New England  
Chapter**

## **EVENT INFO:**

ISPE Boston Area Chapter and the PDA New England Chapter are pleased to reunite again to present May's educational event. We've secured two excellent speakers who will help us understand what's needed to bring Engineers and Quality professionals together. Register now for this one of a kind opportunity to meet, exchange ideas and network with a much larger industry cross section.

## **PROGRAM SUMMARY:**

**The Role and Purpose of Data - Before, During and After Qualification** (Sylvan Poeckh)

Computers and data have become ubiquitous in manufacturing technology and in the science of validation. This presentation will use controlled storage and monitoring as a primary example to discuss and examine:

- The prevalence of data and analytics in equipment design and manufacturing
- Leveraging available data to make better decisions toward purchasing, qualification and operation
- How validation and maintaining compliance are reliant on data integrity and quality
- How data and qualification provide a bridge between design and implementation
- The importance of robust data management systems for data monitoring and retention

**Effectively Integrating the Concepts and Principles of Quality by Design (QbD) and QRM into the Life Cycle of Manufacturing Systems** (Paul Stanovich)

This presentation will demonstrate how to implement the ASTM E2500 standard as a framework for the specification and design and verification of systems, with a focus on early involvement of the quality and validation units throughout the requirements definition and design phases of systems in order to ensure product quality and patient safety. The presentation will also show the effective use of design review and risk assessment to improve system design and formulate a verification strategy based on SME input. With this approach, true quality oversight involves much more SME level interaction than simply review and signature approval.

## **SPEAKERS:**

**Sylvan Poeckh** is the Director of Validation for the Pennsylvania branch of Masy BioServices. He has worked in the pharma/biotech industry for over 22 years, with the past 15 years in a validation services role. His validation experience includes qualification and project management for numerous global Fortune 500 companies. Notable examples include Building Automation Systems, Distributed Control Systems for filling and packaging lines, data logging systems, and hundreds of environmentally controlled chambers. Sylvan is a Bachelor of Science in Information Systems degree candidate at Albright College.

**Paul Stanovich** is the Managing Partner and Senior Consultant at Process Design Solutions (PDS) and PDS Sandbox. Paul has over 20+ years of engineering consulting and executive level management experience at multiple global Engineering and Validation companies successfully delivering professional services to the pharmaceutical, biotech, and medical device industries. The PDS companies provide process and automation engineering, QbD/QRM, process/product development/design solutions for Single Use Technology (SUT) end users and suppliers alike. Paul is an expert in the development, execution, management of engineering/design, commissioning, qualification and validation strategies, plans, and programs. Paul also has an extensive experience and expertise in the implementation of current and new industry trends and best practices such as ASTM E2500, GAMP 5, ICH Q8, Q9, and Quality by Design (QbD) in engineering.

*ISPE Boston Area Chapter and PDA New England Chapter Present:*  
**Validation: The Bridge Between  
Engineering & Quality Assurance**

**Wednesday, May 17, 2017**

5:30 pm to 9:00 pm

***Hilton Boston/Woburn***

2 Forbes Road, Woburn, MA 01801



**ISPE**®

**Boston Area  
Chapter**

Serving All of New England



**New England  
Chapter**

**WHO SHOULD ATTEND?**

This educational session will be of great value to individuals who hold GxP relevant roles in Manufacturing, Engineering, Quality and Validation

**PROGRAM SCHEDULE:**

5:30-6:30 PM – Registration, networking, appetizers

6:30-7:00 PM – Sit-down Dinner

7:00-7:15 PM – Announcements

7:15-8:00 PM – Presentation #1, 10 minutes for Q+A

8:00-8:45 PM – Presentation #2, 10 minutes for Q+A

8:45-9:00 PM – Networking

**DIRECTIONS:**

**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:**

**Michael Levesque**, GE Healthcare

**Brian Hagopian**, Clear Water Consulting, Inc.

**Howard Sneider**, CRB

*ISPE Boston Area Chapter and PDA New England Chapter Present:*  
**Validation: The Bridge Between  
Engineering & Quality Assurance**

**Wednesday, May 17, 2017**

5:30 pm to 9:00 pm

***Hilton Boston/Woburn***

2 Forbes Road, Woburn, MA 01801



**ISPE**®

**Boston Area  
Chapter**

Serving All of New England



**New England  
Chapter**

**REGISTRATION FEES:**

**Registration by  
5/10/2017**

**Registration After  
5/10/2017**

<input type="checkbox"/> ISPE Members	\$75	\$115
<input type="checkbox"/> ISPE Young Professional Members	\$35	\$45
<input type="checkbox"/> Non-members	\$95	\$135
<input type="checkbox"/> ISPE Student Members	FREE	FREE

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

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](mailto:office@ispeboston.org)

**\*\*PLEASE NOTE: CANCELLATIONS RECEIVED AFTER MAY 10, 2017 ARE SUBJECT TO BILLING\*\***