

*ISPE Boston Area Chapter Presents:*  
**Data Integrity and Your Software Vendor**

**Thursday, April 12, 2018**

5:30 pm to 9:00 pm

Worcester Polytechnic Institute  
Gateway 1, 1<sup>st</sup> Floor, Room 1002  
60 Prescott Street  
Worcester, MA 01609-2280



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**EVENT INFORMATION:** Join the Boston Area Chapter of the ISPE and find out where software tools in the life science industry are headed! Presentations will follow [ISPE's Annual Student Poster Contest](#), and will conclude with a live discussion and Q&A session. A networking reception and refreshments will precede the program. ISPE's latest GAMP® Guide on Records & Data Integrity will be on display. Register today!

**PROGRAM SUMMARY:**

Attend a live program at WPI in Worcester, MA on computer system validation, managing vendor relationships, and use of as-a-service (XaaS) applications within the life sciences industry. Most companies have procedures for managing the life cycle of their computerized systems, but many have been using the same processes for years and have not taken measures to modernize. Our speakers will discuss the integration of vendor management, risk assessment, and assessment of regulatory applicability into your computerized system validation (CSV) program. Featuring a speaker from both the software vendor perspective and the perspective of an industry consultant, this event will focus on discussion related to maintaining good data integrity throughout the lifecycle of your software. Learn ways to make your CSV program smarter, and more efficient, user-friendly, and cost-effective!

**WHO SHOULD ATTEND:**

Validation Engineers, Information Technology, Quality Engineers and Quality Assurance Professionals, Compliance Professionals, QC Microbiology and Contamination Control Professionals, and anyone responsible for maintenance or ownership of a software system within their organization.

**PART 1: XaaS – Managing “As-a-Service” Vendors in the Life Sciences Industry**

Increasingly more options are made available to life sciences professionals looking for software tools to streamline, improve quality, and increase throughput in their operations. While regulations applicable to computer systems have changed very little in the past 10 years, technologies continue to develop and improve, while the methodologies previously used to manage and implement software remain the same. Our speaker will explore a variety of measures – from risk assessment to integrating vendor management into your computer system validation program – that can help ensure confidence in your system and its vendor.

**SPEAKER:**

**Kosal Keo, CEO, Boston Technology Research**

Kosal is the CEO and Co-Founder of Boston Technology Research Corp. He has 20+ years Compliance and Quality systems experience in the Health Science and Technology industry, including 7+ years of leadership experience in IT Quality, Compliance and Security. An entrepreneur at heart, Kosal co-founded two consulting

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firms in the Bio/Pharma and medical device industry, an IT infrastructure company (Kendall IT Solutions) and was a co-founder and managing partner in a Venture Capital firm. Kosal graduated with a B.S. degree in Biotechnology from University of Massachusetts at Lowell.

## **PART 2: Software Vendor Roles and Responsibilities in the Life Sciences Industry**

Meeting regulatory requirements, (both Part 11 as well as the relevant GxP regulations) in laboratories requires excellent knowledge of the tools (software and instruments) supplied by outside vendors. As the compliance expert for a vendor of CDS and software (with over 40,000 users, mostly in regulated pharmaceutical laboratories) for over 25 years, Heather regularly receives questions from laboratories about the vendor's roles and responsibilities in that environment. Regulated labs, additionally, are leveraging other critical GxP services, such as Infrastructure or “compute” to outside service providers. Clearly defining how a vendor, such as a cloud services provider, can support a regulated company is critical for life sciences customers. This presentation will highlight example questions that get asked of vendors and service providers, and suggest possible answers or approaches to get the information needed to answer regulatory questions.

### **SPEAKER:**

**Heather Longden, Senior Marketing Manager, Waters**

After a number of years in training, supporting and selling Waters Software, Heather's current role is as a specialist in compliance to e- record regulations, acting as a resource to the global informatics community at Waters and the users of all Waters informatics products. This involves helping design the compliance into our informatics products and services, attending and presenting at specialist conferences, keeping up to data on the latest interpretations and amendments to the regulations and disseminating this information to the Waters field and corporate organizations.

Heather also manages the global Empower Product Management team. This team has significant responsibility for supporting our global customer base and managing the backlog of feature enhancements and defect fixes requested by our customers for inclusion in future releases.

### **MEETING MANAGERS:**

**Christopher Ciampa, Young Professional Meeting Manager, Thermo Fisher Scientific**

**Bob Wherry, Shire, Lexington, MA**

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**PROGRAM SCHEDULE:**

5:30 – 6:30 PM Registration and Networking Reception  
6:30 – 6:40 PM Introductions  
6:40 – 8:30 PM Presentations  
8:30 – 9:00 PM Q&A

**REGISTRATION FEES:**

	<b>Registration by 4/5/2018</b>	<b>Registration After 4/5/2018</b>
<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Young Professional Members	\$20	\$30
<input type="checkbox"/> Nonmembers	\$95	\$115
<input type="checkbox"/> 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 APRIL 5<sup>TH</sup> ARE SUBJECT TO BILLING\*\***

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**DIRECTIONS AND PARKING:**

Onsite parking is free. All attendees must place a parking placard, which will be sent in confirmation e-mail, on dashboard of their car. Walk-ins will receive a placard upon onsite registration.

***Getting to Campus:***

**From the East (Mass. Turnpike, including Logan Airport)**

Take Mass. Turnpike (I-90) to Exit 11A (I-495). Proceed north to exit 25B (I-290), then west into Worcester. Take Exit 18 (Lincoln Sq., Rte. 9). Turn right at end of ramp, bear right (again) onto Concord St., and take an immediate right onto Prescott St.

**From the East (Rte. 9)**

Follow Rte. 9 to Worcester. After crossing I-290, proceed downhill to Lincoln Sq. Bear right onto Lincoln St., getting into the middle lane. At the next set of lights, turn left onto Concord St. and take an immediate right onto Prescott St.

**From the North**

Take I-495 south to I-290. Follow directions from east (Mass. Turnpike). Take Exit 18 (Lincoln Sq., Rte. 9). Turn right at end of ramp, bear right (again) onto Concord St., and take an immediate right onto Prescott St.

**From the South and West**

From western Massachusetts and Connecticut: Take I-84 to Mass. Turnpike (I-90). Take Exit 10 (Auburn) and proceed east on I-290 into Worcester. Take Exit 17 (Lincoln Sq., Rte. 9). Turn left at end of ramp and follow Rte. 9 west, downhill, to Lincoln Sq. Bear right onto Lincoln St., getting into the middle lane. At the next set of lights, turn left onto Concord St. and take an immediate right onto Prescott St.

***Directions to the Parking Lot:***

Take your first right onto Washburn Way. Follow parking signs to the North Lot which will be to your right after the parking garage. The gates are on "auto". Once you enter the gate will recognize your car and the arm of the gate will open. It will do the same when leaving. Also, across the street is another smaller visitor lot; you may park there. Please be sure to place your placard on the dash of your car.

***Parking options include:***

Parking lot adjacent to the Parking Garage

The WPI Visitors Lot is adjacent to Gateway Park I (60 Prescott Street).

Park on far side of 50 and 60 Prescott Street, across from both Gateway Park buildings.

Park on Washburn Street, the street behind the two Gateway Park buildings and in front of the parking garage.