

*ISPE Boston Area Chapter Presents:*  
**Cloud Computing**  
**New Challenges in Data Integrity and Security**

**Thursday, November 13, 2014**

5:30 pm to 8:30 pm

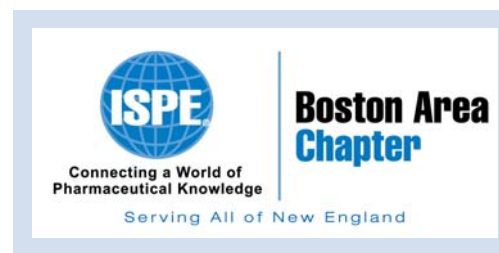
***Cubist Pharmaceuticals Inc.,***

65 Hayden Ave, Lexington, MA

**OR VIA SIMULCAST AT**

***Crowne Plaza Hotel Providence - Warwick***

801 Greenwich Street, Warwick, RI 02886



**EVENT INFORMATION:**

Attend the live program at Cubist Pharmaceuticals in Lexington, MA or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI. The programs at both locations will include a networking reception including appetizers

**PROGRAM SUMMARY:**

In 2011, the FDA began their ICT21 Initiative for 21st century cloud-based computing in an effort to drive down costs and increase efficiencies. Likewise, pharmaceutical, biotechnology and medical device companies have slowly begun outsourcing some of their GxP computing needs. Currently, there are cloud-based offerings being used within various companies in research, regulatory submissions, materials inventory, building management, labeling and recalls. Our panel of speakers will quickly review the basics of cloud computing in the life science industries, and then discuss how to meet the regulatory requirements and challenges for validation, data integrity and security.

The panel, composed of representatives from small and large Life Science organizations, will discuss the concerns, challenges, risk mitigation techniques and future of cloud computing and data integrity including:

- The Current Paradigm and How We Got Here
- Cloud-Based Computing – The Basics
- Having Someone Else Hold Your Data – The Concerns and Challenges
- Regulatory and Compliance Concerns – Data Integrity
- Validation – Objectives, Strategy, & Realization
- FDA Perspectives on Cloud Computing & Data Integrity
- The Future – What's Next

**SPEAKERS:**

**Tracy Lampula, Associate Director – Global Information Services (GIS) Compliance  
Vertex Pharmaceuticals, Inc.**

Since joining Vertex Pharmaceuticals, Inc. in February 2003, Tracy Lampula has held multiple roles within the Global Information Services (GIS) group, including leading Computer Systems Validation and IS Governance Teams. She has led and continues to lead process improvement activities in the area of System Life Cycle (SLC), Access Management, and Change Control that support innovative implementation approaches and emerging technologies (e.g. cloud services, mobility) with a focus on GxP, SOX, and Data Privacy compliance.

Prior to joining Vertex, Ms. Lampula worked for several technology-based companies. Tracy received a BA from Clark University.

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### **SPEAKERS CONTINUED:**

**William Sanborn, Director of Information Technology,  
LFB-USA, Framingham, MA**

William Sanborn is the Director of Information Technology with LFB USA, Inc. Bill has 30 years of experience in IT working in several industries including manufacturing of building management technologies, industrial tagging and labeling, stationary products and Biotechnology. Most recently, Bill has held various diverse senior IT roles in the Biotechnology industry that include ERP system implementations, IT Infrastructure and support services, Manufacturing and Quality systems support, various IT Business partnership roles and the IT aspects of mergers, acquisitions and divestitures. In his current role Bill is working with LFB USA to improve efficiencies by introducing newer IT technologies to improve processes while at the same time ensuring that the business is compliant with the multitude of industry regulations.

**Robert Streit, Senior Manager, Q&C Architecture and Design  
Johnson & Johnson**

Robert Streit is a Sr. Manager with Johnson & Johnson Quality & Compliance possessing 24 years of extensive experience in IT working with engineering, quality, manufacturing & control systems inclusive of MES. This work has included defining solutions for multiple regulated environments, developing system requirements, establishing computer systems validation plans, and creating support models for critical systems. More recently, efforts have been focused on establishing compliant approaches for emerging technologies, particularly Cloud and Mobile Technologies. More specifically, this has involved vendor evaluations and establishing supplier compliance requirements, both for assessments and contracted service agreements.

**Robert J. Wherry, MSc MS CPGP CQA CPIP, Principal Consultant, Strategic Compliance Services  
PAREXEL International**

Bob has 30+ years of FDA-regulated industry experience with expertise in process development, process validation, computer system validation, regulatory affairs, regulatory operations, quality assurance, corporate compliance, and quality systems regulations. Bob has lectured on computer validation, biotechnology, regulatory affairs and quality assurance issues at various conferences. He has co-authored three *Pharmaceutical Technology* articles on computer validation and sterility assurance validation, and has contributed to the editing of several computer validation publications.

Bob holds a BS in Chemical Engineering from Lehigh University, an MSc in Pharmaceutical Quality and Good Manufacturing Practice from the University of Strathclyde, and an MS in Regulatory Affairs for Drugs, Biologics, and Medical Devices from Northeastern University. He also has certifications from ISPE and ASQ. He was a Member and Vice-Chairman of the PMA/PhRMA Computer Systems Validation Sub-Committee, and is a current Member of the ISPE GAMP Americas Committee and the ISPE Boston Area Chapter Educational Programs Committee.

### **MEETING MANAGERS:**

**Binesh Prabhakar, Cambridge IT Compliance LLC**

**Christopher Ciampa, Thermo Fisher**

**Heather Longden, Waters**



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**PROGRAM SCHEDULE: Applies to both sites**

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

6:30 – 8:30 PM Presentations

**REGISTRATION FEES:**

	<b>Registration by 11/6/2014</b>	<b>Registration After 11/6/2014</b>
<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Young Professional Members	\$20	\$30
<input type="checkbox"/> Non-members **	\$95	\$115
<input type="checkbox"/> Students Members	FREE	FREE
<input type="checkbox"/> Simulcast in Rhode Island	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](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, 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 November 6<sup>th</sup> ARE SUBJECT TO BILLING\*\***

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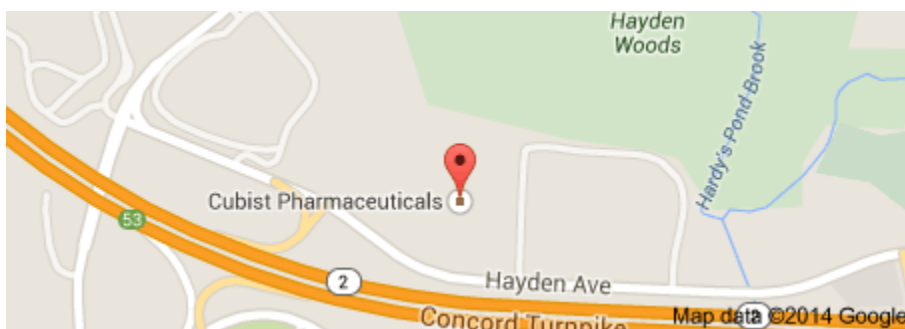
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**DIRECTIONS AND PARKING:**

Ample parking is available in the surface parking lots.

Map of location:



From I-95 North, Take Route 2 East,

Take Exit 53, Take Spring St to Hayden Ave,

Cubist campus is on your left.

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**To the Crowne Plaza Hotel Providence – Warwick, RI:**  
For door to door directions, click [here](#)

<http://www.crownehotelwarwick.com/index.cfm/page/Contact-Us/pid/10269>

