

ISPE Boston Area Chapter Presents:
**Data Integrity:
Part 11 is the Least of Your Problems**

Thursday, June 16, 2016

5:30 pm to 9:00 pm

The Crowne Plaza - Warwick

801 Greenwich Street, Warwick, RI 02886

OR VIA SIMULCAST AT

WPI LSBC, 60 Prescott Street, Worcester, MA 01605

OR VIA SIMULCAST AT

Redhook Ale Brewery, 1 Redhook Way, Portsmouth, NH 03801

OR VIA SIMULCAST AT

Tufts Gordon Institute, 200 Boston Avenue, Medford, MA 02155



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EVENT INFORMATION:

You are invited to attend a live program on Data Integrity with a focus on the recent FDA draft guidance for "Data Integrity and Compliance with CGMP." The event will be held at the Crowne Plaza in Warwick, RI, and simulcast at the WPI LSBC in Worcester, MA; the Redhook Ale Brewery in Portsmouth, NH; and the Tufts Gordon Institute in Medford, MA. Each venue will feature a networking reception with refreshments and a live Q&A after the presentation. Register now to stay up-to-date on the new FDA guidance!

PROGRAM SUMMARY:

"Data Integrity" is more than just a buzzword. With the recent release of the FDA's draft guidance for "Data Integrity and Compliance With CGMP" this April, it is apparent now more than ever that the pharmaceutical industry still has room to grow when it comes to understanding the serious risks associated with the generation, handling, and archival of GMP data. The continued issuance of warning letters, consent decrees, and other regulatory action around data integrity has led some organizations to rethink control of their data. In this program, we will get two different perspectives on the issue: one from an industry expert equipment vendor who leads the industry in Part 11 compliance with over 25 years of experience; the other from a consultant with more than 30 years of experience working to improve GxP compliance in the pharmaceutical, biotechnology, and medical device industries. To conclude the program, our speakers will open up the discussion to the audience for questions and answers.

WHO SHOULD ATTEND:

QA/QC, IT, Validation, Regulatory, Engineers, Auditors, Compliance officers, Lab managers, automation engineers, laboratory and computer systems validation engineers, and any individual responsible for generating or handling data.

Continued on next page...

SPEAKERS:

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 with 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 Waters' informatics products and services, attending and presenting at specialist conferences, keeping up to date 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.

Robert Wherry, Principal Consultant, PAREXEL International

Principal Consultant, Strategic Compliance Services at PAREXEL. Certified ISPE CPIP. Previously with Sunovion, Sepracor, and Rhône-Poulenc Rorer. Thirty-plus years' experience in the pharmaceutical, biotechnology, and medical device industries, with expertise in Quality Systems, GxP regulations, ERES/CSV and Part 11 compliance, Regulatory Operations and eCTD, aseptic processing, process validation, and QSR production and process control. MSc in Pharmaceutical Quality from University of Strathclyde and MS in Regulatory Affairs from Northeastern University. BS in Chemical Engineering from Lehigh University.

MEETING MANAGERS:

Jack Champion, The Hart Companies

James Hughes, Shire

Brijesh Patel, Shire

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PROGRAM SCHEDULE:

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

6:30 – 8:30 PM Presentations

8:30 – 9:00 PM Q&A Session

REGISTRATION FEES:

	Registration by 6/9/2016	Registration After 6/9/2016
<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
<input type="checkbox"/> Simulcast in Worcester, MA	FREE	FREE
<input type="checkbox"/> Simulcast in Portsmouth, NH	FREE	FREE
<input type="checkbox"/> Simulcast in Medford, MA	FREE	FREE

** Attendees may only attend one program as a nonmember.

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 JUNE 9TH ARE SUBJECT TO BILLING****

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Crowne Plaza Hotel Providence - Warwick

801 Greenwich Street, Warwick, RI 02886

DIRECTIONS:

To the Crowne Plaza Hotel Providence – Warwick, RI:

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

For door to door directions, click [here](#)

SIMULCAST LOCATIONS:

WPI Life Sciences Bioengineering Center

60 Prescott Street, Worcester, MA

For door to door directions, click [here](#)

Redhook Ale Brewery – Alemaker's Hall

1 Redhook Way, Portsmouth, NH 03801

For door to door directions, click [here](#)

Tufts Gordon Institute

200 Boston Avenue, Medford, MA 02886

For door to door directions, click [here](#)



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