

ISPE Boston Area Chapter Presents:
**Risky Business:
How Quality Systems and Risk Blend**

Thursday, March 19, 2015

5:30 pm to 8:30 pm

Shire Human Genetic Therapies

Fortis Lecture Hall

200 Shire Way, Lexington, MA 02421

OR VIA SIMULCAST AT

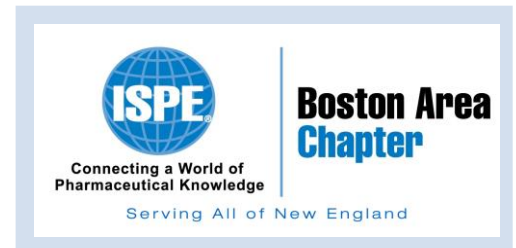
Crowne Plaza Hotel Providence - Warwick

801 Greenwich Street, Warwick, RI 02886

AND in a NEW SIMULCAST LOCATION AT

WPI Biomanufacturing Education and Training Center at Gateway Park

50 Prescott Street, Worcester, MA 01605



THANK YOU TO OUR PROGRAM SPONSOR



EVENT INFORMATION:

Attend the live program at Shire Human Genetic Therapies in Lexington, MA or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI or at the WPI BETC at Gateway Park in Worcester, MA. The programs at all locations will feature a networking reception including appetizers.

PROGRAM SUMMARY:

Have you ever wondered about how risk approaches integrate across different quality systems? What does the FDA think of risk assessments? Do they just justify not doing work or are they a tool to quantify the risk associated with decisions and focus work on the most impactful portions of the business. How should risk be viewed, especially when looking across different quality systems? Is risk in a silo or do we integrate risk across different quality systems? Why is risk in change control so different than deviations? Come ready to hear some thoughts from an FDA speaker and then bring questions for our panel of an FDA speaker and industry expert.

TOUR:

The ISPE Boston Area Chapter is also glad to present a rare opportunity to tour Shire's 400 Shire Way manufacturing facility in Lexington utilizing single-use technologies at commercial scale.

Membership has its privileges!

This tour is open only to ISPE Members and will fill up fast! So register early!

Please check-in at Fortis Lecture Hall at 200 Shire Way, Lexington and you will be given your tour group schedule.

Tours start at 4:30PM and the last tour leaves at 5:15PM.

Continued on next page...

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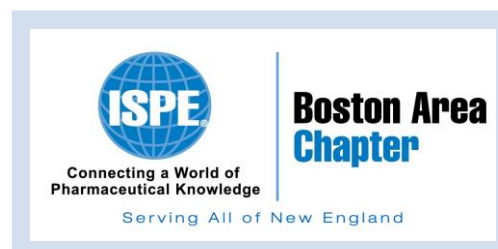
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SPEAKERS:

Edmund Mrak, Drug Specialist, New England District of Food and Drug Administration and member of FDA's Pharmaceutical Inspectorate

He conducts domestic and foreign drug manufacturing quality inspections and pre-approval inspections on the majority of prescription drug manufacturers and other complex or high risk pharmaceutical operations including biotechnology and aseptic processes. Mr. Mrak has been with the FDA for over seven years and joined FDA with over ten years of prior experience in the pharmaceutical industry where he led the manufacture of solid oral, liquid, and sterile drug products. Training includes extensive topics from FDA and a BS in Biology and MS in Teaching Biology, both from the State University of New York at Plattsburgh, NY, USA.

Xach Kibbie, Senior Risk Program Manager, Quality Risk Management Department, Shire

He has 15 years of industry experience, performing risk assessments on production equipment and control systems, business continuity, embedding risk into validation master plans, and tech transfer efforts. Recently, he was responsible for the global design and leadership at a consent decree site to successfully implement risk operationally in all areas. Xach has also lead efforts in validation program management, tech transfer, and operations strategy. Xach has a bachelors from Lesley and is currently attending the MIT Sloan Executive Certificate Program, where he holds a certificate in Business Continuity and Crisis Management.

MEETING MANAGERS:

Eric Felz, Shire

Mike Foshey, UMass Dartmouth

Nagmeh Salimi, Northeastern University

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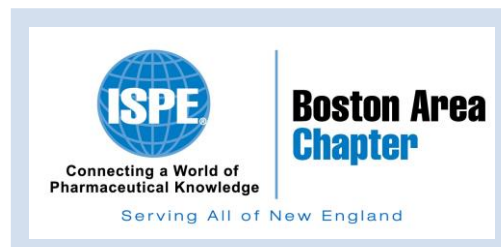
Crowne Plaza Hotel Providence - Warwick,

801 Greenwich Street, Warwick, RI 02886

AND in a NEW SIMULCAST LOCATION AT

WPI BETC at Gateway Park, 50 Prescott Street,

Worcester, MA 01605



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PROGRAM SCHEDULE:

4:30 – 5:15 PM Members Only Tours (tours will be staggered every 15 minutes)

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

6:30 – 8:30 PM Presentations

REGISTRATION FEES:

	Registration by 3/12/2015	Registration After 3/12/2015
<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 Warwick, RI	FREE	FREE
<input type="checkbox"/> Simulcast in Worcester, MA	FREE	FREE
<input type="checkbox"/> MEMBERS ONLY TOUR	Included	Included

** 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 MARCH 12 ARE SUBJECT TO BILLING****

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EVENT AND TOUR LOCATION:

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200 Shire Way, Lexington, MA 02421

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

SIMULCAST LOCATIONS:

Crowne Plaza Hotel Providence - Warwick

801 Greenwich Street, Warwick, RI 02886

To the Crowne Plaza Hotel Providence – Warwick, RI:

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

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

WPI BETC at Gateway Park, 50 Prescott Street, Worcester, MA 01605

To the WPI BETC at Gateway Park – Worcester, MA:

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

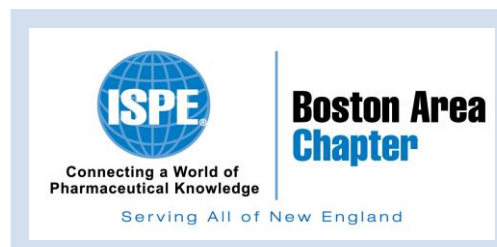
Take Mass. Turnpike (I-90) to Exit 11A (I-495). Proceed north to exit 25B (I-290), then west into Worcester. Take Exit 18 (Lincoln Sq., Rte. 9). Turn right at end of ramp, bear right (again) onto Concord St., and take an immediate right onto Prescott St. Take your first right onto Washburn Way and follow past the The WPI Life Sciences and Bioengineering Center (which will be the building on your left). Visitor parking is next to the building.

From the East (Rte. 9)

Follow Rte. 9 to Worcester. After crossing I-290, proceed down the hill 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. Take your first right onto Washburn Way and follow past the The WPI Life Sciences and Bioengineering Center (which will be the building on your left). Visitor parking is next to the building.

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. Take your first right onto Washburn Way and follow past the The WPI Life Sciences and Bioengineering Center (which will be the building on your left). Visitor parking is next to the building.



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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, down the hill, 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. Take your first right onto Washburn Way and follow past the The WPI Life Sciences and Bioengineering Center (which will be the building on your left). Visitor parking is next to the building.

Parking options include:

Parking lot adjacent to the Parking Garage

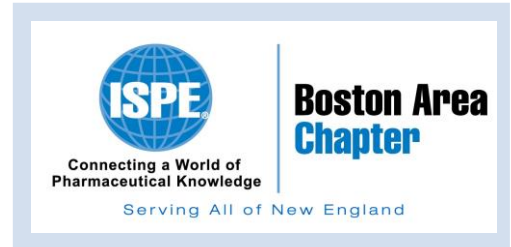
The WPI Visitors Lot is adjacent to Gateway Park I (60 Prescott Street).

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.

Please pay close attention to no parking signs to avoid being ticketed.

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



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