

Co-Sponsored by ISPE Boston Area and New England Chapters:
Streamlining Extractables & Leachables Data
YES! Someone HAS Done This Before, and We Have the Data to Prove It!

Thursday, June 16, 2011

Abbott Bioresearch Center

100 Research Drive, Worcester, MA 01605

PROGRAM:

Do you find yourself being asked to provide leachables and extractables data, and wondering where to begin? Learn how to share data and knowledge with other industry professionals to save valuable time and resources, and allow yourself to focus on your process.

The Extractables and Leachables Safety Information Exchange (ELSIE) is a consortium of pharmaceutical, biotech, and medical device companies that is developing a database that will hold (i) safety information on extractables and leachables from a variety of materials; and (ii) controlled extraction study information from materials used in container closure systems, devices, and bioprocessing. The ELSIE database offers a number of valuable potential benefits including reducing duplicative safety studies, streamlining the search for safety information for extractables and leachables. It also provides E & L information that companies can use early in their development, to reduce the risk of resource-draining leachables issues arising at the end of development. Ultimately this will help companies deliver high quality drug products to patients in a timely manner. During the ISPE seminar, ELSIE representatives will provide background on leachables and extractables, review the consortium's key priorities and recent progress, and demonstrate the Safety Information Database.

MEMBERS ONLY TOUR (45-minutes):

The 460,000 square foot main building at Abbott Bioresearch Center houses biopharmaceutical research and production. See key areas related to the multi-product production facility; including, the *first floor utility area* to view pure water systems, chillers, boilers and water treatment, and a *neutral corridor* (minimal gowning) view into clean room production areas (cell culture, purification and glass wash).

SPEAKERS:

William P. Beierschmitt, PhD, DABT

Bill received his BS in Biology from Mount Saint Mary's University, and his PhD in Toxicology from the University of Maryland. After completing post-doctoral work at the University of Connecticut Toxicology Program, he joined Pfizer's Drug Safety Research and Development department in Groton, Connecticut. Bill is a Diplomat of the American Board of Toxicology. In his over 20 years experience in the pharmaceutical industry, Bill has been involved in a wide range of toxicology issues associated with impurities in drugs, including the development of strategies to risk assess extractables and leachables.



Connecting a World of
Pharmaceutical Knowledge

**Boston Area
Chapter**



Connecting a World of
Pharmaceutical Knowledge

**New England
Chapter**



Connecting a World of
Pharmaceutical Knowledge

**Boston Area
Chapter**

**THANK YOU TO OUR
PROGRAM SPONSORS**



CRITICAL AUTOMATION SOLUTIONS



Waters

THE SCIENCE OF WHAT'S POSSIBLE.™



WPI

Dr. Arthur Shaw

Dr. Shaw is currently working as an independent consultant. In 2010 he retired from Pfizer Inc. where he had held a number of positions in both the Pharmaceutical Sciences and Medical Device Divisions. In 2005 he established the Pfizer Extractable and Leachables Laboratory at Pfizer. He holds a BS and MS from Northeastern University, and PhD degree from Purdue University in Chemical Engineering. Dr. Shaw is a team member of the PQRI Parenteral and Ophthalmic Drug Product team and is a consultant for the Extractables and Leachables Safety Information Exchange (ELSIE) Consortium.

MEETING MANAGERS:

Peter Fox, RoviSys

Joshua Froimson, Abbott Bioresearch Center

Michael Levesque, Olympus Biotech Corporation

Co-Sponsored by ISPE Boston Area and New England Chapters:
Streamlining Extractables & Leachables Data
YES! Someone HAS Done This Before, and We Have the Data to Prove It!

Thursday, June 16, 2011
Abbott Bioresearch Center
100 Research Drive, Worcester, MA 01605



**Boston Area
Chapter**



**New England
Chapter**

PROGRAM SCHEDULE:

(Networking Reception and Program are open to Members and Non Member. Tour is Members only)

4:45 – 6:30 PM Registration and Networking Reception
5:00 – 5:45 PM Members Only Tour of Abbott Bioresearch Center
6:30 – 8:30 PM Program

REGISTRATION FEES:

Registration by 6/9/2011

After 6/9/2011

<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Yes! I'm a Member and will be attending the TOUR.		
<input type="checkbox"/> Non-members	\$95	\$115
<input type="checkbox"/> Students	\$5	\$10

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, 411 Waverley Oaks Road, Suite 331B, Waltham, MA 02452

Telephone: 781-647-ISPE (4773) ☒ Fax: 781-647-7222 ☒ Email: ispe@camihq.com

****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER June 9th ARE SUBJECT TO BILLING****

Co-Sponsored by ISPE Boston Area and New England Chapters:
Streamlining Extractables & Leachables Data
YES! Someone HAS Done This Before, and We Have the Data to Prove It!

Thursday, June 16, 2011
Abbott Bioresearch Center
100 Research Drive, Worcester, MA 01605



**Boston Area
Chapter**



**New England
Chapter**

DIRECTIONS:

ABC (Abbott Bioresearch Center) Main Entrance:

- From the East:
 - Mass Pike (I-90) West
 - Exit 12, Framingham/Rt. 9
 - Route 9 West toward Worcester
 - You will cross over Lake Quinsigamond as you enter Worcester
 - Turn right onto Plantation Street at the second light after Lake Quinsigamond
 - First left onto Research Drive Right at 2nd drive into ABC parking area
- From the North:
 - Take I-190 South
 - I-290 East
 - Right off exit onto Plantation Street
 - Right at third light onto Research Drive (at the Beechwood Hotel sign)
 - Right at 2nd drive into ABC parking area
- From the West:
 - Mass Pike (I-90) East
 - Exit 10 onto I-290 East
 - Exit 15 onto Shrewsbury Street
 - Merge onto Route 9
 - Left at next light onto Plantation Street (Beechwood Hotel on the left)
 - First left onto Research Drive Right at 2nd drive into ABC parking area

PARKING:

Parking will be in the lot in front of the main entrance at ABC. Overflow parking will be available at the Beechwood Hotel (closest two rows) and the Farmhouse, a UMass facility next to the Beechwood.

