

ISPE Boston Area Chapter Presents:
**Serialization Regulations and Technology:
Navigating the New Demands of the Distribution Chain**

Thursday, December 13, 2012

5:30 pm to 8:30 pm

Hyatt Regency Cambridge

575 Memorial Drive

Cambridge, MA 02139



PROGRAM SUMMARY:

The Biopharmaceutical Industry is quickly adopting new technology to secure the drug distribution chain, help assure patient safety, comply with evolving regulations, and enhance the bottom line.

...*And starting at the bottom line*, a local industry analyst (IDC Tech Insights, Framingham) has identified \$11 billion in "revenue leakage" that might be reduced by better drug tracking. Stopping the leaks means discouraging diversion from distribution channels, maintaining safe delivery of cold-chain products, and enhancing management of product recalls. Recent recall events in the news have heightened awareness of the criticality to maintain pace with the new serialization technologies and stay ahead of regulatory deadlines.

Evolving standards and regulations both in the US and internationally will soon require all saleable units to have an "e-Pedigree" with real time track-and-trace capability. Track-and-trace allows health care providers to verify critical drug information that helps ensure patient safety. The challenge to Biopharma is big! Fortunately, the technology is emerging quickly, with improved integration that provides robust solutions.

Learn how a national tracking and authentication service uses cloud technology to aid in data sharing.

Attendees at this meeting will learn from industry experts who know the regulations *and* the technology. Attendees will see case studies with examples that deliver real business benefits and assure compliance.

If you are developing new medicines, manufacturing drug products, or distributing them, this meeting applies to you - don't miss it! Come join us and hear industry experts describe what World-Class companies are doing now!

SPEAKERS:

Mark Hallowell, Barry-Wehmiller Design Group, Director Engineering

Mr. Hallowell has decades of experience in packaging and process automation controls in the pharmaceutical, medical device, and biotech industries. His experience covers Project Management, Packaging Line Control Philosophy and Design, Computer Systems Validation including 21 CFR Part 11 compliance remediation, Master Planning, and Serialization implementation. The experience in Panel Design, Network Communication Architecture, PLC and SCADA design/programming including data extraction and data analysis, coupled with

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SPEAKERS Continued:

component selection and packaging line commissioning provides complimentary skills required to successfully provide integrated solutions. He is responsible for all aspects of electrical engineering and controls integration associated with automation for the pharmaceutical industry and has implemented numerous Sterilization projects for Big Pharma clients to support pending regulatory requirements. Mark's experience delivering integrated solutions incorporating various technologies (2D & 3D barcodes, RFID, etc.) into complex packaging lines for a wide range of presentations (Vials, Syringes, bags, etc.) and OEM suppliers adhere to customer specifications as related to general design guidelines, hardware preferences and software development. He works with clients to select control system technology, communication protocols, and developing electrical specifications.

Mike Salinas, M+W U.S., Inc., Director of Manufacturing Technology

Mike Salinas is Director of Manufacturing Technology for M+W U.S., Inc. He has over 25 years of diverse production, process development, facilities planning, design, project management and construction experience for Owner Operating and Engineering Design & Construction firms. At M+W, he specializes in applying consistent, leading-edge manufacturing technology and converting technological know-how into feasible, compliant and operationally efficient design concepts for M+W's global Life Sciences clients. Mike will provide a general overview of Serialization, discuss the elements for full implementation, and offer some insights on the challenges associated with implementation. Mike earned a Bachelor of Science in Industrial Engineering (BSIE) degree from Columbia University, New York, and a Master of Science in Engineering Management (MSEM) degree from Drexel University, Pennsylvania.

MEETING MANAGER:

Bill McCarthy, DECCO

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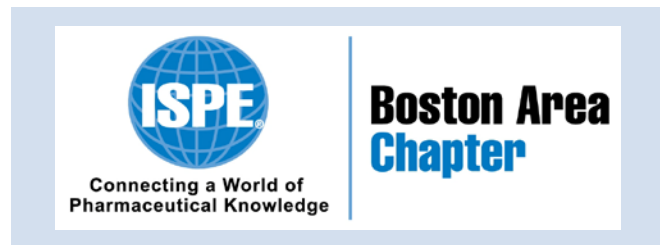
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PROGRAM SCHEDULE:

5:30 – 6:20 PM Registration & Networking Reception

6:20 – 6:30 PM Welcome & Program Introduction

6:30 – 8:30 PM Program

REGISTRATION FEES:

Registration by 12/6/2012 After 12/6/2012

<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Non-members **	\$95	\$115
<input type="checkbox"/> Students	\$5	\$10

** 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.

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

****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER December 6th ARE SUBJECT TO BILLING****

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DIRECTIONS:

From the West:

From Mass Pike: Take exit 18 - Allston/Cambridge (left hand exit).

Follow the signs for Cambridge. Cross the River Street Bridge, exit right at the end of the bridge onto Memorial Drive. Hyatt is 1/2 mile up on Memorial Drive (Route 3) on the left hand side. Turn left at the traffic light to access our Cambridge Hyatt entrance and parking garage.

From the South:

From I-93: Take exit 26 - Storrow Drive/Back Bay/Cambridge.

Stay in the right lane (Storrow Drive). Go 3/4 mile and take second exit on left, Government Center/Kendall Square. Go up the ramp and stay in the right lane. Turn right at the stop sign; go across the Longfellow Bridge. Take the first right off bridge and turn onto Memorial Drive (Route 3). Stay on Memorial Drive approximately 1 mile on right, at light turn right. Hyatt is on your left.

From the North:

From I-93 or Route 1: Take exit 26 - Storrow Drive and follow "FROM THE SOUTH" directions.

From Logan International Airport (BOS, 1 Harborside Drive, Boston, MA 02128):

Follow signs to the Mass Turnpike: 90 Boston/Williams Tunnel. Pay toll upon exiting airport. You will be heading West on 90. From 90 West, take exit 20 Brighton/Cambridge (pay another toll). Out of the toll booth, bear right following sign for Cambridge/Somerville exit. From this exit ramp, stay straight through two lights and cross over the bridge. Just over the bridge, turn right at the light onto Memorial Drive. Stay in the left lane. Continue up/over overpass keeping in left lane. At the first light on Memorial Drive make a left and then another quick left into the Hyatt front circle.

