

ISPE Boston Area Chapter Presents:
Paperless Systems, Lessons Learned

Thursday, February 15, 2018

5:30 pm to 9:00 pm

Bristol-Myers Squibb

38 Jackson Road
Devens, MA 01434



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EVENT INFORMATION:

Dealing with too much paper and looking for a better way to manage it? Join ISPE Boston Chapter for an evening at BMS. Gain knowledge about digitization of paper processes from two perspectives – a performance consultant’s expertise, and an end user’s experience. Enjoy complimentary hors d’oeuvres and a virtual tour of BMS prior to the presentation. Register **TODAY** for this event.

PROGRAM SUMMARY:

Changing to a new software program is the easy part, but implementing a paperless validation system serves as more of a challenge. At this program, hear first-hand accounts from both a commissioning agent and owner to understand how the implementation can be effective – from the “why,” to the implementation, to the organization, and how the transition ultimately benefits the whole team. This session will cover both a case study and the experience of a pharmaceutical company who lived it. Register to attend today and take advantage of the lessons they learned.

WHO SHOULD ATTEND:

Anyone dealing with volumes of documents and cumbersome paper flow processes should be here. Everyone who works in automation, IT, quality, process engineering, and operations should be interested in this session. All are welcome!

PART 1: Lessons Learned

Pharmaceutical companies are driven by one primary mission – to increase the quality of patients’ lives through technology and innovation. BMS Devens started with digitized manufacturing and laboratory processes to increase efficiency, elevate the level of regulatory compliance, and achieve operational goals. A representative from BMS, the industry leader in the digital movement, will present the company’s lessons learned as they embarked on their digital journey with paperless vision since 2006. The presentation will cover topics from realization of paperless vision to the knowledge gained through experience, making it a valuable discussion for individuals in any company size.

SPEAKER:

Nancy Poirier, Associate Director, Manufacturing Engineering, Bristol-Myers Squibb Company

Nancy has been with Bristol-Myers Squibb for 8 years, beginning her tenure as a Manufacturing Engineering contractor responsible for start-up activities. In 2013, she converted to a full-time employee and has been in her current position for the past three and a half years. Prior to working at BMS, Nancy worked as a senior engineer at CRC Consulting and GlaxoSmithKline (formerly ID Biomedical), and working as an engineer on the floor

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for Wyeth BioPharma. She graduated from Tufts University with an MS in Chemical Engineering and BA in Chemistry from Lake Forest College.

PART 2:

Benefits Electronic Validation Lifecycle Management (eVLM) systems: A Case Study

Electronic Validation Lifecycle Management (eVLM) systems have begun to disrupt traditional document-based validation processes. eVLM systems are designed to create value for companies that manufacture biopharma products and medical devices by helping these companies improve quality, reduce cost and manage risk.

This presentation will provide an in-depth case study of how a eVLM system was employed to assist an emerging biotech firm design and validate a new manufacturing facility. We will look at the goals that motivated the company to adopt a paperless validation system, compare/contrast the paperless and paper-based systems for each of the major steps in the validation process, and we will assess how the paperless validation system measured up against the company's goals. We will wrap up by sharing lessons learned from companies who have adopted paperless validation systems, and a guide to help you assess if a paperless validation system would be a good fit for your company.

This presentation will be of particular interest to managers, engineers and analysts responsible to plan, build, commission and operate facilities for the manufacturing pharmaceuticals and medical devices – particularly in the areas of quality validation, quality assurance, procurement, information systems, design engineers and capital project managers – as well as consultants who support these activities.

SPEAKER:

Charlie Maher, Executive Director, Performance and Reliability, Commissioning Agents, Inc.

Charlie Maher is the Managing Director of BioVoke with overall responsibility for product development and commercial growth. Charlie has led large, complex C&Q projects for Commissioning Agents, Inc. and has experience in business development for SaaS products. Charlie previously served in the submarine force of the United States Navy where he commanded a nuclear-powered submarine and served as the Chief of Staff of the Naval Undersea Warfare Center, the Navy's R&D facility for undersea weapon systems. Charlie has graduated with an MBA from the Sloan School of Management, a MA in National Defense & Strategic Studies from the Naval War College, as well as a BS in Physics and a BA in History from the University of Notre Dame.

MEETING MANAGERS:

Janelle Carretero, New England Controls

John Sheridan, PMA Consultants

Kevin Keating, Massachusetts Biologic Laboratories

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PROGRAM SCHEDULE:

Registration opens at 5:00 PM – we recommend early arrival

- 5:30 – 6:30 PM Registration and Networking Reception
- 6:30 – 6:40 PM Introductions
- 6:40 – 7:10 PM Virtual Tour of BMS Facility
- 7:10 – 8:30 PM Speakers Presentation
- 8:30 – 9:00 PM Q&A

REGISTRATION FEES:

| | Registration by 2/8/2018 | Registration After 2/8/2018 |
|---|-------------------------------------|--|
| <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 |

Please note that due to BMS security protocols, walk-ins will not be accepted.

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 FEBRUARY 8TH ARE SUBJECT TO BILLING****

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DIRECTIONS AND PARKING:

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

Plenty of parking is available on site. All attendees must check-in with BMS security.



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