

*ISPE Boston Area Chapter Presents:*  
**“Engineers and Project Managers:  
Blending Skills for a Common Goal”**

**Thursday, December 12, 2013**

5:30 pm to 8:30 pm

**Biogen Idec**

14 Cambridge Center, Bio 8 Auditorium  
Cambridge, MA 02142



**PROGRAM SUMMARY:**

In the biopharmaceutical industry, almost every project requires a Project Manager (PM) and an Engineering Professional. Although both work towards a common goal they don't necessarily see “eye to eye” using the same success criteria. Many such differences stem from each person's experience, perspective and responsibilities.

Engineers honor their professional rigor and best practices. Project managers balance the best interests of stakeholders and functional areas, while meeting the triple constraints of scope, cost, and schedule to deliver a high quality product, service or result.

This program will address ways for the PM and the Engineer to work better to meet the overall objectives of a successful project. The use of various tools, techniques and enhanced overall project knowledge will be the focus.

**PRESENTATION ONE: Project Engineering Under ASTM E2500**

We first examine the role of the GMP Project Engineer in light of ASTM E2500, ICH Q8, and ICH Q9. These guides require the involvement of a subject matter expert (SME) with a technical understanding of the critical aspects of manufacturing to drive specifications, design and verification, using QRM (Quantitative Risk management) throughout.

Partnering a Project Engineer with a Project Manager can help bring the required SME perspective. The PE and PM have different skills and focus which, when combined, can lead to more efficient and effective project delivery. The project manager can focus on the business aspect and administrative tasks while the project engineer can focus on GEP (Good Engineering Practice) and the technical aspects related to product quality. A review of the PM tool WBS (work breakdown structure) will also be provided.

**SPEAKER ONE:**

**Andrew Faden, CPIP, PMP** is a consultant in Project Management, Validation, and Controls and Automation. He received his BS in Electrical Engineering from UMass Amherst, and his MS in Bioscience Administration from Worcester Polytechnic Institute. Andrew gained experience in industrial controls as an Applications Engineer at Klockner-Moeller and Siemens Energy and Automation. In 1996 he took this experience to AstraZeneca, Westborough, MA, where he managed facilities and equipment projects in their parenteral manufacturing plant in support of new product launches. In 2011 he began a contracting career, providing both validation and project management services to pharmaceutical manufacturing clients in Southern California, Colorado, and Massachusetts. After receiving his CPIP, Andrew helped facilitate the Spring 2013 CPIP Study Group.

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**PRESENTATION TWO: PM Competency for Successful Projects**

Project management competency is critical for engineers and engineering teams. Engineers contribute to the delivery of project outcomes within the triple constraints (schedule, cost, scope) while delivering a quality output within resource constraints.

Engineers are critical to the success of projects that involve process or product design, setting up new facilities, process development, manufacturing process automation, product or technology transfer from process development to internal or external manufacturing, and IT infrastructure projects. Engineers are innovative in designing new processes, making improvements to processes/products, developing flawless systems, or conducting detailed root cause analysis of failures.

Yet engineers tend to overlook the big picture when they work on project teams in delivering such initiatives. Engineering teams need to understand the changing dynamics of project lifecycles, project management processes, the significance of people side of projects, managing stakeholder expectations and aligning with other cross functional groups. Project management is an under-utilized tool, where engineering can create significant value by driving the project outcomes.

The second session will highlight two key aspects of project management capabilities that the engineering groups must definitely focus on before they kick off a cross functional project. First is Project Concept and Feasibility (highlighting design and execution/implementation risks), and second, Planning People Management (Project Organization, Stakeholder Management and Communication).

**SPEAKER TWO:**

**Neeraj Shah, MBA, PMP, SAPM** is the Associate Director of IT for Global Supply Chain and Manufacturing at Shire Pharmaceuticals and volunteers as the Director of Education at Boston APICS Chapter #10. He is a regular speaker on Project Management at conferences organized by APICS, Mass Bio Council, and NESCON Conferences, and is the chief instructor of the "Project Management Professional Certification Workshop", for the Boston Chapter of APICS.

Over 18 years Neeraj has successfully orchestrated and delivered business solutions by leading complex cross functional projects spanning supply chain, finance, quality, IT, validation, regulatory and engineering. His core competency lies in project management, leadership, strategy development, stakeholder management and senior management interfacing skills with a strong focus on business process management and integrating projects with organizational goals.

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**SPEAKER TWO Continued:**

Neeraj has worked in multiple supply chain disciplines within Bio-Pharmaceutical, as well as multiple industry verticals such as CPG, High Tech, etc., for organizations like Shire Pharmaceuticals, Biogen Idec, Welch's, General Electric, General Motors, etc.

Neeraj has an MBA from Babson College, PMP, with a BS in Industrial Engineering from Bangalore University, India

**MEETING MANAGERS:**

**Mark Jodoin**, Symbotic, LLC

**Robert Beane**, Barry-Wehmiller Design Group

**John Spohn**, CPIP, Hargrove Life Sciences

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**PROGRAM SCHEDULE:**

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

6:30 – 8:30 PM Welcome and Program

**REGISTRATION FEES:**

	<b>Registration by 12/05/2013</b>	<b>After 12/05/2013</b>
<input type="checkbox"/> Members	\$30	\$40
<input type="checkbox"/> Non-members **	\$55	\$75
<input type="checkbox"/> Students	FREE	FREE

\*\* 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](http://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](mailto:office@ispeboston.org)

**\*\*PLEASE NOTE: CANCELLATIONS RECEIVED AFTER December 5 ARE SUBJECT TO BILLING\*\***

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**DIRECTIONS (click here):**

[http://maps.google.com/maps?f=q&source=s\\_q&hl=en&geocode=&q=14+Cambridge+Center,+Cambridge,+Massachusetts+02142&ll=42.2855,-71.4149&sspn=0.010953,0.019076&ie=UTF8&hq=&hnear=10+Cambridge+Center,+Cambridge,+Middlesex,+Massachusetts+02142&z=16](http://maps.google.com/maps?f=q&source=s_q&hl=en&geocode=&q=14+Cambridge+Center,+Cambridge,+Massachusetts+02142&ll=42.2855,-71.4149&sspn=0.010953,0.019076&ie=UTF8&hq=&hnear=10+Cambridge+Center,+Cambridge,+Middlesex,+Massachusetts+02142&z=16)

**OR**

**From MBTA (The "T"):**

Take the Red Line "T" to Kendall Square/MIT stop. Walk straight up the stairs.

**From North or South:**

Rte. 93 to the Storrow Drive Exit. Follow signs for Storrow Drive. Take Storrow Drive to Exit marked Kendall Square. Go across Longfellow Bridge over Charles River. Once you cross the Charles River, the road turns into Broadway.

**From Waltham & Route 2:**

Rte. 2 to Memorial Drive eastbound. (You will pass Harvard University, The B.U. Bridge, The Mass Ave. Bridge and MIT.) After passing MIT, stay to the right. Take left at first set of lights (2nd Kendall Square sign) onto Binney Street. Take left at 2nd light onto Third Street. Proceed to end and turn right onto Broadway.



**From Mass Ave:**

Follow Mass Ave. onto Main Street. Take left onto Ames Street at Legal Seafood.

**From West & Mass Pike:**

Take Mass Pike to Exit 18 (Cambridge/Allston/Brighton Exit). After toll, bear right (Cambridge/Somerville). Go straight across River Street Bridge. Turn right onto Memorial Drive eastbound. After passing MIT, stay to the right. Take left at first set of lights (2nd Kendall Square sign) onto Binney Street. Take left at 2nd light onto Third Street. Proceed to end and turn right onto driveway.

**PARKING:** On street parking meters are free after 6PM.

The closest Parking Garage, “Central Parking System,” is at 4 Cambridge Center where parking is \$18 for up to three hours and \$24 for over three hours.