

Education and Training:

Keynote

•	Gain insight from project leaders and pharmaceutical industry experts who have successfully enacted unique	The Culture of Exceptional Project Management, People Do Make the Difference Gil Stevens, Senior Director, Engineering, Pfizer
•	approaches to project management. Discover the strategies and tactics that make these projects exceptional across the industry, and complementary to an organization's culture. Learn about tools and	Attend concurrent educational sessions by industry experts. Confirmed speakers include: <i>Alignment of Project Management with Organizational Culture</i> Bill Goode, VP of IT, Informatics, and Operations, Jounce Therapeutics Matthew Khair, Project Manager, CRB <i>Strategies and Tactics for Exceptional Project Management</i> Joyce Chiu, PMP, CPIP, Senior Project Manager, Corning Life Sciences Dick Priester, Principal, Strategic Facility Planning, LLC
	approaches to delivering projects efficiently and effectively.	<i>Tools and Techniques for Effective Project Management</i> Sam Spata, AIA, Owner, Principal, Method Lean Steve Marr, Head of Capital, Takeda
	Networking:	Capitalize on opportunities to meet and connect with clients, develop new associations, and solidify existing partnerships. Meet with members and associates of the Boston area ISPE chapter.
	Vendors:	Meet industry-leading solution providers and explore how their products and services can help you achieve project success.
	STUDENT POSTER CONTEST:	View the entries to the ISPE Boston Area Chapter Student Poster Competition. Learn about and discuss the research findings of local ISPE students at the undergraduate and graduate level.
	CHAPTER AWARDS PRESENTATION:	Join us as we formally recognize and celebrate achievements within the ISPE Boston Area Chapter.

Keynote:

The Culture of Exceptional Project Management, People DO Make the Difference

The hallmark of an exceptional project is often defined by the people involved as one having an excellent "culture". The culture of a project can be defined as an integrated pattern of human knowledge, belief, and behavior that exhibits common outlooks, attitudes, values, goals, and customs. In this talk we will explore what the many differentiators of culture in project execution and methods to create and maintain the inclusion and engagement throughout a project's life cycle.

Gil Stevens, Senior Director, Engineering, Pfizer



Gil Stevens is a member of the Pfizer Global Engineering Leadership Team and is currently overseeing expansion of Pfizer's Bio-Manufacturing, Research and Development site in Andover, Massachusetts. With over 25 years' experience in Biopharmaceuticals, Gil has been directly involved in greater than \$2B of facility expansion projects. Over that time, he has held positions of increasing accountability ranging from project specific roles to leading Engineering functions accountable for delivery of large project portfolios. Gil has successfully lead teams through a myriad of projects with technical, cost and schedule driven challenges. He fundamentally believes the key to exceptional project management is through the effective engagement of people and the nurturing of an inclusive culture. He holds a B.S. Degree in Marine Engineering from Massachusetts Maritime Academy and a M.S. Degree in Mechanical

Engineering from Rensselaer Polytechnic Institute.

	Alignment of Project Management with Organizational Culture	Strategies and Tactics for Exceptional Project Management	Tools and Techniques for Effective Project Management
1:50 - 3:00	Case Studies from a Small Biotech: How Company Culture & Technology Influence R&D Operations at Jounce Therapeutics	Turboshield™ - A Case Study for Shortest Path to Market	Lean is More
	Bill Goode Jounce Therapeutics	Joyce Chiu, PMP, CPIP Corning Life Sciences	Sam Spata, AIA Method Lean
3:20 - 4:30	The Importance of Strong Project Leadership on a Fast- track IPD Project	Creating a Project Culture	The Story Behind Shire/Takeda's 2018 FOYA Winner: Los Angeles Building 8
	Matthew Khair CRB	Dick Priester Strategic Facility Planning LLC	Steve Marr, PMP Takeda

Educational Tracks:

SPEAKER BIOGRAPHIES:

Joyce Chiu, PMP, CPIP



Joyce Chiu, PMP, CPIP has over 15 years of large complex NPI (new product introduction) experience under highly rigorous corporate stage gate development processes. She has successfully taken products from concept, VOC (voice of customer), CTQ (Critical to Quality), utilizing best practices in PQA (Product Quality Architecture – combining design and manufacturing controls) to achieve both "do it right the first time" and "do it fast".

Joyce's project and technical program management experience includes specialty semi-conductor chemicals, single-use Bioprocess disposables, PPE (Personal Protection Equipment), medical and cell culture products for cell therapy and 3D cell culture (ECM, organoid and spheroid) applications. Joyce has a B.S. Chemical Engineering from Cornell University and an MBA from Babson College. She has also been actively involved with ISPE Boston chapter

for over 10 years and served on ISPE COPs.

Turboshield[™] - A Case Study for Shortest Path to Market

Internal product design and development with a global team and a global contract manufacturing base presents a unique set of challenges especially for products that must comply to multiple regional or global regulatory standards. This case study of a thrice-patented, award-winning, backward compatible platform PPE product with three sub-systems that must comply to four regional safety standards, illustrates best practices in project management, design control, engineering rigor, quality and regulatory strategy that ensured a successful and timely global launch.

Bill Goode, PMP



Bill Goode PMP, has worked within the biopharmaceutical industry for over 20 years operating in a variety of roles. Bill began his career at Millennium Pharmaceuticals working with laboratory robotics in Research. His automation career took him to Novartis working in the early days at NIBR building robotic systems for Lead Discovery. In 2006 Bill pivoted, taking a role at Amgen in IT project & program management. After 8 years at Amgen Bill joined Jounce Therapeutics in 2014, at that time a fresh, young startup. He is currently the Vice President of IT, Informatics, and Operations at Jounce, now a public company with 130 staff, where he oversees a number of G&A functions including Lab Operations and Facilities. Bill is a board member for LRIG New England, a non-profit dedicated to educating industry and students on life

science technology. He holds a passion for working within high performing teams on challenging problems and is dedicated to the mission of serving cancer patients.

Case Studies from a Small Biotech: How Company Culture & Technology Influence R&D Operations at Jounce Therapeutics

Every company has a unique culture which can impact the organization positively or negatively given the company's core values, behaviors, and people. This talk will explore how the culture at Jounce Therapeutics, a small Immuno-Oncology Biotech, positively influences how Jounce executes projects and operations staff support the business. The presentation utilizes case studies showcasing how the combination of culture and technology enables a small lean organization to deliver on key infrastructure projects.

Matthew Khair



Matt is a Project Manager at CRB with fifteen years combined experience within the biotech industry. Matt have actively participated in all phases of a biotechnology project including conceptual design and basis of design reports; cGMP design documentation development; factory acceptance testing; commissioning test plan generation and execution; validation support; and onsite startup support. Matt has also actively participated in project execution planning and scheduling for various stages of a biopharmaceutical project.

He currently manages a multi-discipline architectural and engineering design team focused on serving the Maryland life sciences market. His process engineering background uniquely equips him to understand the priorities and challenges of these complex life science projects.

Matt was a recipient of CSE's 40 Under 40 Award in 2017.

The Importance of Strong Project Leadership on a Fast-track IPD Project

Integrated Project Delivery (IPD) is an emerging execution trend to satisfy the cost certainty and schedule drivers becoming commonplace in the life sciences industry. A hallmark of successful IPD execution is strong project leadership and a team-centric culture. This presentation will look at a fast-track IPD project and how respect, trust and collaboration, especially amongst the project leadership team, led to a newly fit-out and qualified facility in 12 months.

Steve Marr, PMP



Steve Marr is the Vice President of Capital within the Global Engineering group at Takeda. Previously, Steve has held positions as Vice President and Head of Capital, Head of Project Delivery and Executive Director of Performance and Reliability Services. Steve has over 30 years of experience leading large organizations, including nine years in key leadership positions on multibillion dollar engineering/construction projects in both the pharmaceutical as well as nuclear industry.

Steve is retired from the Navy with the rank of Captain. He served as a Commander of Submarine Squadron ONE and Commanding Officer of the USS SALT LAKE CITY. He holds a Bachelor of Science Degree in Ocean Engineering from the United States Naval Academy.

The Story Behind Shire/Takeda's 2018 FOYA Winner: Los Angeles Building 8

Takeda's Los Angeles Building 8 was a brownfield project to construct a facility to house the purification of two plasma derived product, as well as a GMP pilot plant for scale-up and production of very small batch orphan drugs such as BabyBIG, an IgG treatment for infant botulism. Products, project background, conceptual design, what made the project unique, key technological and innovative features and project results will be discussed in this interactive session.

Dick Priester



Dick Priester is a Past-President of the Boston Area Chapter, and Past-Chairmen of ISPE, and has made many presentations at ISPE events over the years. He has spent his entire career in the design and construction of process facilities, the last 30 years of which have been in biopharm. During the past 20 years he has acted as Owner's Representative for a large cross-section of clients and projects in the Northeast.

Creating a Project Culture

All companies, whether Owner, Architect, Engineer, Construction, or CQV service providers, have distinct cultures unto themselves. Sometimes these cultures are deliberate and cultivated; other times they are de facto and

inadvertent. When forming a project team to undertake a capital project, project leadership must deliberately meld potentially disparate cultures and create a project culture suited for the project at hand. Although there is not "one size fits all" project culture, the development and nurturing of the optimized project culture is an essential element to team building and alignment, and ultimately the success of the project.

What are the tools, and at what points in the project's life cycle can one best proactively define and implement an optimized project culture? What can you do to assure that the project team does not lose its focus on sustaining it project culture throughout its life cycle.

Sam Spata, AIA



Sam Spata is a registered architect with 25 years' executive experience advising corporate, commercial and institutional Owners on project delivery modes, ranging from Public-Private-Partnerships to Integrated Project Delivery. In 2016 he established Method Lean as an independent consultancy to help Owners, Constructors and Designers use Lean in building High Performance Teams, capable of delivering projects with reliable cost, schedule and value performance.

A past board member of the Lean Construction Institute (LCI), Sam promotes Lean Project Delivery, drawing on skills as an architect, speaker, writer and coach. He has mentored a generation of project managers, sharing his passion

for client service, as evidenced by his decade-long advocacy for the \$1.4bn Javits Convention Center expansion, and multi-project relationship with Bristol-Myers Squibb.

Sam is a frequent public speaker. He has delivered a series of Lean webinars for Columbia University; workshops for LCI at their national Design Forum and Congress; and, a seminar at the International Laboratory Design Conference in Madrid, on Lean Science Facilities.

Sam Spata graduated from the City College of New York. He is an Improved Instructor with LCI and a CES Approved Provider with the AIA. He co-founded both the New York City and New York State chapters of the Lean Construction Institute.

Lean is More

Over the past decade, Lean has entered the project delivery mainstream, providing a range of benefits to Owners, Consultants, Designers and Builders: Reduced Waste; Efficient Flow; and, Enhanced Value.

In this session, attendees learn how Lean theory, processes and tools are essential to efficient and effective project delivery. The audience will gain an understanding of the AEC community's role in Lean Project Delivery and why owners are adopting this approach. The session demonstrates how Lean delivers projects twice as likely to be on budget; three times as likely to be on schedule by focusing on the fundamentals of Waste, Value and Flow. Lean projects achieve increased reliability in schedule, cost and value performance.

THANK YOU TO:

Conference Meeting Managers & Organizers

Howard Sneider, CRB

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PRICING AND DETAILS:

Wednesday, April 10, 2019 Registration opens at 11:30 AM Exhibit Hall Open All Afternoon!

Newton Marriott

2345 Commonwealth Avenue Auburndale, MA 02466

PROGRAM SCHEDULE:

- 11:30 AM: Registration and Networking
- 12:00 PM: Luncheon Keynote
- 1:30 PM: Concurrent Educational Sessions
- 4:30 PM Networking Reception and Awards Presentation

REGISTRATION FEES:

	Registration by April 3, 2019	Registration after April 3, 2019	
□ Member	\$125.00	\$135.00	
□ YP and Student Members	\$85.00	\$95.00	
\square Non-Member	\$195.00	\$210.00	

REGISTRATION IS NOW OPEN ONLINE!

Don't waste time filling in the form! Register online at <u>www.ISPEBoston.org/Events</u>.

Pay by credit card OR check.

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