

ISPE Boston Area Chapter Presents:

Facility Optimization & Process Improvement

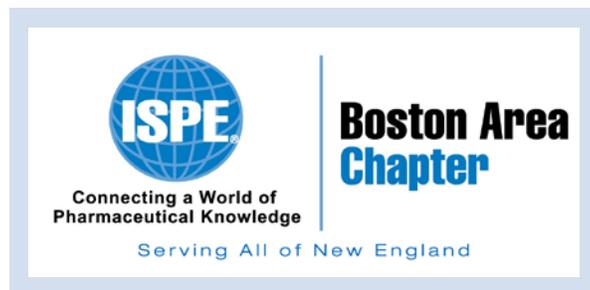
Tours: The Massachusetts Accelerator for Biomanufacturing
at University of Massachusetts Dartmouth (The MAB)

Thursday, April 17, 2014

4:30 pm to 9:00 pm

The MAB

1240 Innovation Way
Fall River, Massachusetts



PROGRAM SUMMARY: Biological products are expanding rapidly from classic mAbs to therapeutic proteins, conjugates, cell therapies and even tissues. Production technologies are evolving rapidly from stainless steel to single use to continuous processes. These changes offer process improvement opportunities not previously possible. Optimizing a production facility to simultaneously support a range of products and technologies, under an open access management approach, to support industry, research and education required many disciplines and compromises at every stage. You will tour the new Massachusetts Accelerator for Biomanufacturing (The MAB) and hear from the design, construction, university and industry team that developed the concept as well as the building.

WHO SHOULD ATTEND: Individuals interested in the challenges in designing and building a multi-product, multi-client facility which also must accommodate a wide range of production technologies, such as stainless steel fermentation, single use cell culture and incubated tissue regeneration, as well as those who face challenges in production that might benefit from experimentation in a GMP-like environment.

TOUR SCHEDULE: Two rounds of one hour tours will be conducted. The first set of tours begins at 4:30 PM and the second set at 5:30 PM. A maximum of 60 people per round can be accommodated. Register early to get the spot you want!

Tour A: Mechanicals and Production Window View – This tour examines up close all the process utilities in the mezzanine and basement for this flexible production facility. Taking advantage of the floor to ceiling windows in a non-qualified production corridor, this tour will also provide excellent viewing of the mammalian and microbial production trains. Finally, the tour will visit the QC, warehouse and teaching labs.

Tour B: Gowned Production Suite plus Mechanicals – Beyond Tour A, this tour explores the production suites by allowing participants to suit up and enter the clean production areas. See what goes on behind the glass walls, inspect the equipment up close and see rooms such as solutions preparation, inoculum and wash/sterilization not visible from the public corridor.

Tour C: Interstitial Space Tour (ISPE Members Only) at 5:15 PM (with either A or B). Put on a hard hat and enter the interstitial space that contains all the piping and ductwork that distributes the utilities to each of the production rooms. You'll see the complexity that benefited from a detailed 3D BIM model.

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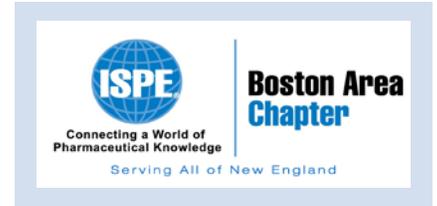


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PRESENTATION:

MAB Facility: Optimization and Process Improvement Opportunities, Presentation and Panel Discussion



In the first hour, speakers will describe the collaborative origins, design, construction and trade-offs of the MAB from their distinct perspectives of the University, industry/users, design and construction teams. The stories will emphasize the facility optimization and process improvements required for this novel, open-access multi-product, multi-client facility. The second hour will feature a moderated panel discussion with audience participation. Explore the design tensions that were balanced, the organizational collaboration required and the opportunities for continued technical improvement and community engagement in the MAB's future.

SPEAKERS (In Order of Appearance):

Mark Trusheim, Co-Bio Consulting

Mark is President of Co-Bio Consulting and Bio-manufacturing Executive in Residence at the University of Massachusetts Dartmouth and a member of the Massachusetts Bio-Manufacturing Roundtable. In 2004 as Interim President and Board Member of the Massachusetts Biotechnology Council, Mark began working with the University of Massachusetts to develop public/private collaborations as part of an integrated strategy to advance biomanufacturing. The \$32M MAB is a key part of that strategy.

As an entrepreneur, Mark founded the diagnostics company Cantata Laboratories after 10 years at Monsanto/Pharmacia, culminating as Co-President and COO of Cereon Genomics, a \$500M collaboration with Millennium Pharmaceuticals. He is a former Special Government Employee for the FDA's Office of the Commissioner. Mark has degrees in Chemistry from Stanford University and Management from the MIT Sloan School of Management.

Paul Vigeant, UMass Dartmouth

Paul Vigeant is President of MAB Inc. and Assistant Chancellor for Economic Development at UMass Dartmouth. Paul has been involved in the conception and leadership of the MAB since 2004. He is also Executive Director of the SouthCoast Development Partnership.

Chris Brigham, UMass Dartmouth

Dr. Chris Brigham is an assistant Professor of Bioengineering at UMass Dartmouth. His interests are in metabolic engineering, biomanufacturing, and microbial physiology and genetics. He received his PhD in Molecular Biology and Microbiology from Tufts University School of Medicine. He then worked as a postdoctoral researcher at MIT, where he studied biomanufacturing of sustainable alternatives to petroleum products using industrially significant bacteria with engineered, optimized metabolic pathways to synthesize value

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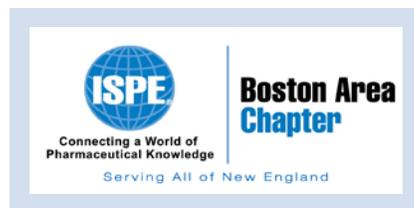
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SPEAKERS Continued:

Chris Brigham, UMass Dartmouth

added products from surplus or waste carbon feedstocks. Dr. Brigham is interested in production of bio-based polymers and fuels using this type of sustainable process. He plans to utilize the MAB to teach Bioengineering students process development and control, hopefully resulting in a “win-win” for UMass Dartmouth students and the biomanufacturing community that utilize the MAB.



Steve Fitzpatrick, DPS Biometrics

Dr. Stephen Fitzpatrick played a leading role in the conceptual planning and design of the Massachusetts Accelerator for Bio-manufacturing (MAB) at U. Mass Dartmouth bringing to the project over thirty years of experience in the biopharmaceutical industry. Dr. Fitzpatrick is President of DPS Biometrics, a Framingham, MA based engineering, architectural and consulting company focused on the biopharmaceutical industry. DPS Biometrics is the lead design firm responsible for the planning and design of the MAB. Over the years, Dr. Fitzpatrick has consulted on the engineering development of several new medicines and technical advances stemming from the biopharmaceutical industry.

Dr. Fitzpatrick holds Bachelor's and Master's degrees in chemical engineering and a Doctorate in biochemical engineering from the University of Manchester, UK and is recipient of the Dista Biochemical engineering prize (Manchester University) and the 1999 Presidential Green Chemistry Award from the US EPA.

Sharon Jozokos, Suffolk Construction

Sharon Jozokos is a Project Executive for Suffolk Construction with more than 24 years of experience in the construction industry. Sharon has extensive experience in the science and technology sector, having played all roles during her career ranging from field superintendent to PX on projects valued up to \$200M for prestigious clients such as MassBiologics, UMass Dartmouth, Beth Israel, and MIT, to name a few. She has managed projects that have been instrumental in cancer and pharmaceutical research, development, and manufacturing.

Sharon was the construction team lead and ultimately responsible for the successful execution of the MAB project in partnership with all team members. A few of those responsibilities include identifying and managing construction milestones with the highest quality expectations, establishing and managing the construction budget, and ensuring we maintain a team approach. Sharon holds Bachelors in Construction Management from Wentworth Institute of Technology and a MBA from Boston College. She was named Woman of the Year by Wentworth in 2013, is a past president of NAWIC (National Association of Women in Construction), elected to the Wentworth Corporation in 2010, and is currently on the board of the Giving Circle, a Suffolk employee run nonprofit foundation.

MEETING MANAGERS:

Joyce Chiu, CPIP, Honeywell Safety Products

Paul Doherty, CRB Builders

Doyle Johnson, Hargrove Life Sciences, LLC

Michael Severino, Festo Corporation



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PROGRAM SCHEDULE:

- 4:30 – 6:30 PM Tours (Register for A, B or C, select 4:30 PM or 5:30 PM)
- 5:30 – 6:30 PM Registration & Networking Reception
- 6:30 – 8:30 PM Welcome and Program

REGISTRATION FEES:

	Registration by 4/10/2014	After 4/10/2014
<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Young Professional Members	\$20	\$30
<input type="checkbox"/> Non-members **	\$95	\$115
<input type="checkbox"/> Student Members	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.

Pay by credit card OR check.

Tour Choice: A B C Tour Time: 4:30 pm 5:30 pm

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 April 10 ARE SUBJECT TO BILLING

Those participating in any tour need to wear sensible clothing and closed-toe, low-heeled footwear. Those entering the clean production suites must gown and follow safety and cleanliness protocols as instructed. Those participating in the Interstitial Space Tour must wear hard hats and other protective gear as instructed.

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DIRECTIONS:

For a map and door-to-door directions go to: <http://goo.gl/maps/DAC6o>

From Boston and points north

- Take I-93 or I-95/Rt 128 South
- To Route 24 South
- Take Exit 8B Innovation Way
- Turn East (Left) and proceed ¼ mile to MAB

From Cape Cod (Bourne Bridge) and points east

- Take Route 195 West through New Bedford, MA
- To Route 24 North
- Take Exit 8B Innovation Way
- Turn East (Right) and proceed 1/8 mile to MAB

From Providence, RI and points west

- Take Route 195 East
- To Route 24 North
- Take Exit 8B Innovation Way
- Turn East (Right) and proceed 1/8 mile to MAB

From Newport (RI) and points South

- Take Route 24 North toward I-195/Fall River/Providence
- Take Exit 8B Innovation Way
- Turn East (Right) and proceed 1/8 mile to MAB

