

*ISPE Boston Area Chapter Presents:*  
**Learning Through Doing:  
The Interplay of Pilot Plant, Product, and Process**

**Thursday, March 24, 2016**

5:30 pm to 9:00 pm

***Shire Human Genetic Therapies***

Fortis Lecture Hall

200 Shire Way, Lexington, MA 02421

**\*If you cannot attend this program, please see last page for re-showing information\***

**EVENT INFORMATION:**

Attend the live program at Shire in Lexington, MA. This program will feature a networking reception including appetizers. As an added bonus, Shire is hosting a tour of the Shire's Pilot Plant Facility. This is an ISPE MEMBER ONLY tour. Tour participation is limited, so register now! There is also a Young Professional's Pre-Meeting available.

**PROGRAM SUMMARY:**

The Pilot Plant plays an instrumental role both in material supply for preclinical and clinical development purposes as well as scale-up of technology and operations. The ultimate goal is developing a solid process that can be successfully transferred to a commercial manufacturing site. In the developing age of customizable, specialized biotechnology therapies, how will Pilot Plants adapt to new technology and what niche will the Pilot Plant play in the future product development lifecycle?

This educational event will include a presentation and panel discussion of Pilot Plant leaders from notable local biotechnology companies. The current and future role of the pilot plant in the product development lifecycle will be examined. The group will first present and comment on benchmarking data collected across their companies. The group will then discuss agility and adaptability of their pilot plants in regards to the current and future pipeline and technologies.

**WHO SHOULD ATTEND:**

This presentation is intended for industry professionals involved in technology transfer, scale-up of manufacturing processes, process development and manufacturing.

**TOUR:**

The ISPE Boston Area Chapter is also glad to present a rare opportunity to tour Shire's 200 Shire Way Pilot Plant in Lexington. Highlights of the tour will include disposable technology and novel purification equipment.

**Membership has its privileges!**

This tour is open only to ISPE Members and will fill up fast! So register early!

Please check-in at Fortis Lecture Hall at 200 Shire Way, Lexington and you will be given your tour group schedule. Tours start at 4:30PM and the last tour leaves at 5:15PM.

**YOUNG PROFESSIONAL'S PRE-MEETING:**

Join the YP's for a pre-meeting session from 4:30PM -5:30PM.



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## **MODERATOR:**

### **Brad Ebel, Manager, Pilot Plant Operations, Shire**

Brad Ebel has been active in the biopharmaceutical industry for over 15 years and has been focusing on the disposable industry for over 12 years. He is the Manager of Upstream and Media production in Shire's Pilot Plant Operation (PPO) Group. While at Shire, he has designed and developed two fully disposable perfusion based cell culture operation facilities; responsible for supporting process development activities up too supplying material for toxicology studies. Previous to Shire, Brad worked for two different manufacturing companies in Colorado where he was active in process development, MFG and media production groups. While in Colorado he helped developed and commission a stainless steel MFG/PD lab from "dirt" to operation in 6 months. In addition, he was able to develop a MFG process in an ISO 7 (100ft<sup>2</sup>) laboratory and later transferred the process to an ISO5-8 (7200+ft<sup>2</sup>) facility that he helped design, oversaw construction and was an active member of the team responsible for commissioning it into a cGMP facility. Brad holds his B.S. in Chemistry for Westminster College.

## **PANELISTS:**

### **Bill Brazier, Senior Manager, Process Development Pilot Plant, Amgen Rhode Island**

Bill has 25 years of biotechnology experience in the areas of Manufacturing, Engineering and Process Development. He began his biotech career at Genentech in Manufacturing with roles that included operations, manufacturing technical support, facility and equipment design and start up. After 10 years he transferred to Immunex in Seattle for a role in Process Development responsible for the design, start up and engineering support of the Process Development Facility in Bothell, WA. In 2002 Immunex was acquired by Amgen and he took on roles in global Process Development and Corporate Engineering responsible for developing corporate standards for equipment design. In 2011 he transferred to Amgen Rhode Island for the position of Sr. Manager of the Pilot Plant.

### **Shaun Grier, Associate Director, Pilot Plant Operations, Shire**

Shaun Grier has over 14 years of experience in Process Development, Clinical Manufacturing, and Pilot Plant Operations. He currently is the Associate Director of downstream processing in Pilot Plant Operations at Shire Pharmaceuticals where he leads a group of downstream specialists responsible for the material production and scale-up of early stage therapeutic candidates. In addition, his group also supports process development and manufacturing.

Prior to taking a role in the Pilot Plant, he spent 5 years in Process Development at Shire as a process development engineer where he contributed to the development of several early stage purification processes. He also has led the technology transfer efforts for several processes to internal and external manufacturing along with regulatory file authoring. Before joining Shire in 2006, Shaun held positions in clinical manufacturing and Pilot Operations at Wyeth Biopharma. Shaun holds a B.S in Biology and Chemistry from Fitchburg University and a M.S in Biotechnology Management from the University of Maryland University College.

### **Christof Schulz, Principal Scientist and Senior Group Leader of Scale-up Laboratory, AbbVie Bioresearch Center**

Christof Schulz has over 15 years of experience in the Biotech industry. After obtaining his Ph.D. in Biochemical Engineering, Dr. Schulz worked as a Postdoctoral Scientist in Bioprocess Research and Development at Eli Lilly and Company in Indianapolis, IN. In 2003, Dr. Schulz joined the Abbott Bioresearch Center (now AbbVie Bioresearch Center) in Worcester, MA as a Scientist in Process Sciences. At Abbott and AbbVie, he has been holding positions with increasing responsibility, currently as Principal Scientist and Senior Group Leader of the Process Sciences Scale-up Laboratory.

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**Dave Sullivan, Director – Bioprocess R&D, Pfizer**

David Sullivan is a Director in Pfizer's Bioprocess R&D Organization responsible for leading the Non-GMP Pilot Plant and development lab support organization. Pfizer's Bioprocessing Pilot Plants, located in Andover, MA and Chesterfield, MO, support both early and late stage biologic and vaccine process development. The primary outputs of the organization include regulatory toxicology and development study drug substance, 100L-1000L process characterization / scale up studies, and implementation of advanced manufacturing processes and process analytical technologies.

David has held a number of diverse roles within the large scale commercial/clinical manufacturing and process development since joining Pfizer in 2004. Prior to Pfizer, he spent 4 years at Bayer Healthcare as a member of their nucleic acid and infectious disease diagnostics unit. David received a B.S. from Worcester Polytechnic Institute and an M.S. from Tufts University.

**Kelly Wiltberger, Associate Director Manufacturing, Biogen**

Kelly currently oversees Biogen's single-use Flexible Volume Manufacturing (FVM) facility in RTP, NC following over a decade leading the pilot scale teams in various capacities. She collaboratively designed and started up the upstream and downstream RTP pilot scale labs. She managed Pilot Scale Cell Culture Development across three separate sites, successfully integrating the San Diego site into RTP and Cambridge in 2011. She was the RTP Technical Development department site lead, spearheaded the initiative to align equipment and procedures between the RTP and Cambridge labs, and was instrumental in implementing the disposable bioreactor technology now used in FVM. Kelly has played key roles in the development of Advanced Process Control (APC) technology and the N-1 perfusion platform, both of which have recently been successfully implemented into large scale manufacturing processes. Under her leadership, the Pilot Scale group worked extensively on bioreactor characterization and process understanding, collaborating both internally and externally to improve scale-up capabilities and modeling of manufacturing processes.

Kelly holds a BS degree in Chemical Engineering from the University of Rochester as well as an MBA from UNC Chapel Hill and has been a co-author on numerous scientific publications.

**MEETING MANAGERS:**

**Stacy Price**, Shire

**Eric Felz**, Shire

**Chris Ciampa**, Thermo Fisher Scientific

**\*If you cannot attend this program, you are invited to our Re-Showing:**

**Thursday, March 31, 2016**

5:30 pm to 9:00 pm

**RE-SHOWING OF 3/24 PROGRAM AT**

***WPI Biomanufacturing Education and Training Center at Gateway Park***

50 Prescott Street, Worcester, MA 01605

**RE-SHOWING OF 3/24 PROGRAM AT**

***Tech Collective – Providence***

166 Valley Street, Providence, RI 02909

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**PROGRAM SCHEDULE:**

- 4:30 – 5:15 PM      Members Only Tours
- 4:30 – 5:30 PM      Young Professional’s Pre-Meeting
- 5:30 – 6:30 PM      Registration and Networking Reception
- 6:30 – 8:30 PM      Presentations



**REGISTRATION FEES:**

	<b>Registration by 3/17/2016</b>	<b>Registration After 3/17/2016</b>
<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
<input type="checkbox"/> <b>MEMBERS ONLY TOUR</b>	Included	Included
<input type="checkbox"/> <b>Young Professional’s Pre-Meeting</b>	Included	Included

\*\* Attendees may only attend one program as a nonmember.

**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, 465 Waverley Oaks Road, Suite 421, 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 MARCH 17<sup>th</sup> ARE SUBJECT TO BILLING\*\***

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**DIRECTIONS:**

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



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