

ISPE Boston Area Chapter Presents:
**Single Use:
From Toddler to Adolescent**

Thursday, May 19, 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



THANK YOU TO OUR
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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 Shire's Pilot Plant Facility with an emphasis on single use implementation. This is an ISPE MEMBER ONLY tour. Tour participation is limited, so register now!

PROGRAM SUMMARY:

Single use was an emerging, breakthrough technology a decade ago. After justifying capital savings and operational efficiencies, Biotech has adopted single use as a mainstream manufacturing approach. Our industry has learned a great deal about additional challenges that present themselves when implementing single use in various configurations and in combination with more traditional manufacturing approaches. Come to find out first-hand the experiences of two industry experts who have witnessed the progression of single-use from toddlerhood to adolescence, and who have uncovered previously hidden considerations. Our speakers will enrich their accounts with actual examples from a pilot plant.

WHO SHOULD ATTEND:

Vendors, service providers, integrators and users of single use technology will all benefit from this event.

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 single-use 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.

PART 1: Uncovering Hidden Costs Behind Implementing Effective Single Use Technology

As Biotech and Pharmaceutical companies continue to increase their dependence on Single Use Technologies (SUT), effective integration of QRM and SUT is paramount to ensuring both project and operational success. There are several key elements to ensure an effective integration into current engineering, materials management/supply chain, manufacturing operations and quality assurance business systems. Project success also depends on providing the framework for a life-cycle based approach toward SUT implementation. These key programmatic elements will be outlined and through the combination of direct project/practical experience

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and programmatic development, Mark McElligott will demonstrate robust, effective and sustainable methodologies for reducing risks associated with SUT integration.

SPEAKER:

Mark McElligott, Partner/Principal Process Engineer, Process Design Solutions and PDS Sandbox

Mark McElligott is the Founder of PDS Sandbox, as well as, Partner and Principal SU Engineer with PDS Consulting which are companies providing Single Use technical engineering, QbD/QRM, process/product development/design solutions for Single Use Technology (SUT) end users and suppliers alike. Mr. McElligott has 18+ years of experience in the biopharmaceutical, medical device and pharmaceutical industries and his consulting expertise is focused on SUT engineering for cGMP Manufacturing Operations, SUT Implementation feasibility assessments, Leachables and Extractables Program Development, Material Science Evaluations, Process Optimization/Debottlenecking, QbD/QRM and Product/Process Development. Mark has developed and successfully implemented life-cycle based SUT programs across the globe by working with end-users and suppliers to establish appropriate and relevant requirements supporting patient safety and product quality.

PART 2: Adaptation of Single-Use Technology in Pilot Plant Operations

Development laboratories utilizing disposable/single-use technology are beneficial because of their lower initial capital expense, faster turnaround times, flexibility to run multiple products in the same facility and reduction of product cross-contamination risk. However, single-use technology also comes with multiple challenges. Shire's development laboratory predominantly runs perfusion-based cell culture for multiple weeks using two different types of cell retention technologies: centrifugation and Alternating Tangential Flow (ATF) filtration. This presentation will focus on the challenges encountered transferring these two sciences from the small-scale development laboratory to the single-use pilot laboratory. By the end of the presentation you will have a better understanding of the following:

- How the adoption of single-use systems significantly alters the development model.
- The design and development required to integrate single-use systems into your facility
- How to partner with your selected single-use vendor(s) to achieve success

SPEAKER:

Brad Ebel, Manager, LSDL, Shire Pharmaceuticals

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, manufacturing 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 developed a manufacturing process in an ISO 7 (100ft²) laboratory and later transferred the process to an ISO5-8 (7200+ft²) cGMP facility that he helped design, provide construction oversight, and commission. Brad holds his B.S. in Chemistry for Westminster College.

MEETING MANAGERS:

Joyce Chiu

Chris Opolski

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

Thursday, May 26, 2016

5:30 pm to 9:00 pm

RE-SHOWING OF 5/19 PROGRAM AT

WPI Biomanufacturing Education and Training Center at Gateway Park

50 Prescott Street, Worcester, MA 01605

RE-SHOWING OF 5/19 PROGRAM AT

Redhook Ale Brewery

1 Redhook Way, Portsmouth, NH 03801

RE-SHOWING OF 5/19 PROGRAM AT

Tech Collective

166 Valley Street, Providence, RI 02909

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PROGRAM SCHEDULE:

- 4:30 – 5:15 PM Members Only Tours
- 5:30 – 6:30 PM Registration and Networking Reception
- 6:30 – 8:30 PM Presentations

REGISTRATION FEES:

	Registration by 5/12/2016	Registration After 5/12/2016
<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"/> MEMBERS ONLY TOUR	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.
 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 MAY 12th ARE SUBJECT TO BILLING****

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DIRECTIONS:

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



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