

ISPE Boston Area and New England Chapters Present:
**Single-Use Systems for Biopharmaceutical Manufacturing:
The End User's Perspective**

Thursday, June 21, 2012

Shire Human Genetic Therapies

Fortis Lecture Hall

200 Shire Way, Lexington, MA 02421

PROGRAM SUMMARY:

Single-use systems offer critical benefits to the end users in the form of lower initial capital expenditures, reduced cleaning requirements, faster turnaround times, reduced risk of product cross-contamination and shorter installation/implementation times. However, these benefits are coupled with a number of challenges. The program is designed to provide the end users' perspective on the development and large scale commercial use of single-use systems. Attendees will gain an understanding of the challenges encountered with single-use systems during technical development, design, startup and routine operational use as well as strategies to address these at various stages of deployment.

The ISPE Boston Area and New England Chapters are also glad to present a rare opportunity to tour Shire's manufacturing facility in Lexington utilizing single-use technologies at commercial scale.

Membership has its privileges!

Please note: The Members only tour portion of this event has reached capacity.

If you have any questions please email office@ispeboston.org.

SESSION I: Development of Process Technology Platforms based on Single-Use Systems

Presented by: Christopher Adams, Shire HGT, Associate Director of Pilot Operations

The session will provide key considerations for the development of process technology platforms based on single-use systems. The presenter will share knowledge and real-life experience gained through design, development and integration of single-use systems in support of an end-to-end fully disposable cell culture process. Based on the lessons learned, key points to consider and a holistic approach to facilitate a thorough upfront evaluation of single-use systems will be reviewed.

SESSION II: Deployment of Single-Use Systems for Large Scale Commercial Manufacturing

Presented by: Mark McElligott, Process Design Solutions, Partner / Principal Engineer

The session will provide an overview for the deployment of single-use systems in commercial large scale manufacturing of biopharmaceuticals. The presenter will share knowledge and hands-on experience gained

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SESSION II Continued:

through the startup and routine operational support of a fully disposable large scale cell culture facility. The unique challenges encountered during startup of a single-use facility as well as various strategies employed to address routine operational challenges will be reviewed.

SPEAKERS:

Christopher Adams, Associate Director of Pilot Operations, Shire

Chris has been with Shire HGT since 2007 where he has held several positions of increasing responsibility within the Process Development department; from Manager of Bioreactor Operations to his current position as the Associate Director of Pilot Operations. His roles within Shire have lead to his direct involvement in the specification and implementation of single use technologies in both the Process Development and Pilot Scale facilities at Shire. Chris has been a key contributor to the design and operation of Shire's pilot plant utilizing two fully disposable cell culture trains.

Additionally, Chris has over 19 years of experience in Pharmaceutical Research and Development serving in diverse roles ranging from high throughput screening (HTS) to automation engineering for laboratory research systems at a number of operating companies such as Curagen, Bristol-Myers Squibb and Aventis.

SPEAKERS continued:

Mark McElligott, Partner/Principal Process Engineer, PDS (Process Design Solutions)

Mark brings over 14 years of diversified Process Engineering, Single-Use Systems (components and instrumentation) Engineering, Operational Management, ICV Systems Development, and Project Management experience within the biotechnology and pharmaceutical fields to Shire HGT. His experience includes conception to completion engineering (conceptual brief, conceptual design, basic design, detail design, fully integrated commissioning and validation/verification) upstream and downstream process engineering, process development, process equipment/instrumentation design and process utilities system design. Mark's experience in single-use engineering started at Lonza Biologics in 1998 and continued with companies such as Biogen, Wyeth, Cardinal Health, and NNE Pharmaplan. Mark has been representing and leading Shire HGT's single-use engineering initiatives for all upstream manufacturing operations since 2009 as a contract senior process engineer.

MEETING MANAGERS:

Mert Aktar, Shire HGT

Peter Fox, Rovisys

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PROGRAM SCHEDULE:

4:00 – 5:30 PM Tours **SOLD OUT** (*Tours will be staggered every 5 to 10 minutes and will last 30 minutes.*)
5:30 – 6:20 PM Registration and Networking Reception
6:20 – 6:30 PM Welcome and Program Introduction
6:30 – 8:30 PM Program

REGISTRATION FEES:

Registration by 6/14/2012 After 6/14/2012

<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Non-members	\$95	\$115
<input type="checkbox"/> Students	\$5	\$10

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, 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 June 14th ARE SUBJECT TO BILLING****

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DIRECTIONS AND PARKING:

From Locations North

Merge onto I-95 South
Merge onto MA-2 E/CONCORD TURNPIKE via EXIT 29A toward ARLINGTON/CAMBRIDGE. 0.9mi
Take EXIT 53 toward SPRING ST./LEXINGTON/WALTHAM. 0.2mi
Turn SLIGHT RIGHT onto CONCORD AVE. 0.1mi
Turn RIGHT onto SPRING ST 0.3mi
Turn LEFT onto SHIRE WAY
End at 200 Shire Way Lexington, MA 02421

From Locations South

Merge onto I-95 North
Take the TRAPELO RD. exit, EXIT 28A, toward BELMONT. 0.3mi
Turn RIGHT onto TRAPELO RD. 0.1mi
Turn LEFT onto SMITH ST. 0.3mi
SMITH ST becomes SPRING ST. 0.4mi
Turn LEFT onto SHIRE WAY.
End at 200 Shire Way Lexington, MA 02421

From Locations West

Merge onto I-90 E/ MASS PIKE/ MASSACHUSETTS TURNPIKE toward JCT I-95/ BOSTON 6.7mi
Take the I-95 N/ RT-30/ RT-128 N exit, EXIT 14, toward N.H.-MAINE/ POINTS NORTH. 1.2mi
Merge onto I-95 North
Take the TRAPELO RD. exit, EXIT 28A, toward BELMONT. 0.3mi
Turn RIGHT onto TRAPELO RD. 0.1mi
Turn LEFT onto SMITH ST. 0.3mi
SMITH ST becomes SPRING ST. 0.4mi
Turn LEFT onto SHIRE WAY.
End at 200 Shire Way Lexington, MA 02421

From Locations East

Merge onto I-90 W/ MASS PIKE/ MASSACHUSETTS TURNPIKE (Portions toll).
Take the I-95/ RT-128 exit, EXIT 15, toward WALTHAM/ DEDHAM. 0.4mi
Take the I-95 N/ RT-30/ RT-128 N exit on the LEFT toward N.H.-MAINE/ POINTS NORTH. 0.5mi
Merge onto I-95 North
Take the TRAPELO RD. exit, EXIT 28A, toward BELMONT. 0.3mi
Turn RIGHT onto TRAPELO RD. 0.1mi
Turn LEFT onto SMITH ST. 0.3mi
SMITH ST becomes SPRING ST. 0.4mi
Turn LEFT onto SHIRE WAY.
End at 200 Shire Way Lexington, MA 02421

Free on-site parking will be provided at the Shire Lexington Campus for the event.