ISPE Boston Area Chapter Presents:

Designing, Building & Operating Manufacturing Facilities for Novel Therapeutics

Thursday, December 6, 2018

5:30 pm to 8:30 pm

Novartis Institutes for Biomedical Research
250 Massachusetts Avenue
Cambridge, MA 02139

ISPE Boston Area Chapter
Serving All of New England

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EVENT INFORMATION:

Join us for an interactive panel discussion that will offer access to experts from leading firms in the gene & cell therapy space, prominent CDMO's and a principal process engineer. Enjoy refreshments and the company of colleagues and friends prior to the educational session.

PROGRAM SUMMARY:

Design of manufacturing facilities for the production of novel therapeutics requires careful planning and consideration of a myriad of factors, such as throughput, biosafety level, product segregation and contamination control, regulatory environment, time to market, and tech transfer challenges. It is a complex mix of elements and requires a project team that can move quickly and effectively to de-risk the investment and meet market demand. Recently, many firms have embarked on ambitious program to bring manufacturing capacity for gene and cell therapies online to meet demand for novel therapeutics.

Learn from experts that have recently delivered or are in the midst of developing facilities and programs for scale up and manufacturing of these novel therapies. Understand the decision points associated with developing internal or combined strategies for delivering to the programs.

WHO SHOULD ATTEND:

This program will appeal to people across the spectrum of Novel Therapeutics, those directly involved or in supporting roles. Individuals or organizations considering manufacture of novel therapeutics should attend as the discussion, which you can influence, will cover planning, design, quality / regulatory considerations and technology platforms utilized.

PANELISTS:

John Dougherty, Principal Process Engineer, DPS Group

John Dougherty is a highly experienced bioprocess engineer and biologics SME with extensive experience in engineering and project management facility designs for biologics and gene therapy facilities. As a lead process engineer at DPS, he is a collaborative change leader and talent developer delivering results in LEAN manufacturing implementation and Root Cause Analysis. John is also a very strong team builder experienced in project development and implementation for capital projects, as well as continuous improvement teams. He has a solid background in cGMP, demonstrated performance with regulatory authorities and inspections, and extensive experience in applied design, operation, maintenance, environmental monitoring, and gowning for clean rooms, and holds a LEAN Six Sigma Green Belt. Prior to DPS John held roles such as Head of Technical Operations at Acambis, MA and Director of Manufacturing at Astra Zeneca in

Continued on the next page…

Westborough, MA. John is a graduate of Drexel University and an active member of International Society of Pharmaceutical Engineers (ISPE).

Bankim Patel, Senior Director, Facilities & Engineering, Moderna

Bankim Patel is the Senior Director, Facilities & Engineering at Moderna Therapeutics. Prior to joining Moderna, Bankim was the Senior Director of Facilities & Engineering at Alexion Pharmaceuticals where he was a member of the Site Leadership Team, responsible for all aspects of facility maintenance and lead a team of engineers to support a cell culture manufacturing facility. While at Alexion, Bankim developed key performance indicators and metrics for use by the facilities team to identify critical gaps, and developed detailed plans to resolve those gaps. Bankim has also worked at ImClone Systems, a subsidiary of Eli Lilly, Bristol-Myers Squibb, and Merck.

Stacy Price, Vice President, Technical Operations, Ziopharm Oncology

Stacy Price has over twenty years of experience managing organizations and programs for commercial & clinical biotechnology operations. She has been responsible for establishing and leading efforts to direct operations and programs for a variety of functions including: Tech-transfer, facility startup, cGMP and Pilot Manufacturing, Engineering, CMC, process development, IT applications, and supply chain. Prior to working at Ziopharm, Stacy was the Head of Operations in the Process Development organization, at Shire Pharmaceuticals, leading business and laboratory groups through strategic planning & execution. Prior to joining Shire she was Site Head and Director of Manufacturing at Transkaryotic Therapies (TKT) and a Senior Process Engineer at Serono Laboratories.

Stacy holds a Master of Science in Biochemical Engineering from Tufts University. She is a Project Management Professional (PMP), has a green belt in Lean Six Sigma and holds a certification in Business Process Management. She has been an ISPE member for 23 years, has led numerous ISPE events, and has previously served on the Board of Directors of the Boston Area Chapter.

Lance Weed, Principal Consultant

Lance Weed has 30 years of extensive experience in the design, construction, process development, manufacturing and establishment of operations for biopharmaceutical facilities including drug substance and drug product lines where no prior manufacturing capability was established. This includes uniQure's multiproduct gene therapy facility utilizing 100% disposable process systems for drug substance and drug product. Lance also built BioVex's oncolytic virus production facility which is currently the commercial production facility for Imlygic under Amgen's ownership. Lance has a degree in Chemical Engineering from University of New Hampshire.

MODERATOR

Jeff Kent, Process Engineer, DPS Group

Jeff Kent is an experienced process engineer with a strong foundation in chemical/biochemical engineering principles and excellent problem solving and analytical skills. Jeff has worked in a broad range of functions in the biotech sector and offers proven abilities in operating/maintaining cGMP purification equipment for commercial manufacturing, selecting and developing primary human cell lines for an R&D laboratory and designing experiments with small-scale bioreactors in support of pharmaceutical cell culture development. Jeff earned his MS, Chemical Engineering from Northeastern University, BS, Biochemical Engineering, Queen's University, Canada and BS, Chemical Engineering, Queen's University, Canada. He is an active member of the American Institute of Engineers and the International Society of Pharmaceutical Engineers (ISPE) Boston Chapter.

MEETING MANAGERS:

Gerry Archambault, Process and Water

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PROGRAM SCHEDULE:

5:00 – 6:30 PM Registration and Networking Reception
6:30 – 8:30 PM Panel Discussion
8:30 – 9:00 PM Q&A

REGISTRATION FEES:

		Registration by 11/29/2018	Registration After 11/29/2018
☐	Members	$50	$60
☐	Young Professional Members	$20	$30
☐	Nonmembers	$95	$115
☐	Student Members	FREE	FREE

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 NOVEMBER 29TH ARE SUBJECT TO BILLING****

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DIRECTIONS AND PARKING:

Click here for door to door directions.

Street parking and garage parking are both available for a fee

Novartis is located within the walking distance of the Central Square Red Line T-stop. Parking is available at the terminal Alewife and Braintree stations of the Red Line.

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