ISPE Boston Area Chapter Presents:

Pushing the Limits: Being Innovative in a Regulated Industry

Thursday, November 15, 2018

5:30 pm to 8:30 pm

ISPE Boston Area Chapter

Serving All of New England

THANK YOU TO OUR PROGRAM SPONSOR

CAI COMMISSIONING AGENTS, INC.

Alnylam

300 Third Street
Cambridge, MA 02142

EVENT INFORMATION: Join the ISPE Boston Area Chapter for an open forum on innovation. Push your own limits by participating in our pre-program activity with pharma colleagues while enjoying refreshments and a cash bar. Please have valid I. D. ready for a security checkpoint. Walk-ins are still welcome to register onsite.

PROGRAM SUMMARY: Innovation comes in many forms ranging from scientific breakthroughs to new technologies and processes. This panel discussion will focus on innovation, and how it impacts the phases of the drug development lifecycle through regulatory compliance. The intent of this discussion is to allow for an interactive look into how innovation can be applied in a regulated field by providing an open forum for the moderator and audience to interact with industry leaders. If you want to better understand how to integrate innovation in your business, or the effects of innovation on your business, this panel will provide much-needed insight. By having people walking the walk of innovation from Development, Engineering, Manufacturing and Regulatory Affairs, we will be able to look to interdependencies, conflict, and synergies of innovative products. Topics will range from technical, personnel, and regulatory decisions needed to incorporate innovation into your business.

WHO SHOULD ATTEND: Development, Engineering, Manufacturing, Quality Assurance and Regulatory Affairs personnel. Anybody that wants to better understand how to develop and execute teams when implementing innovative platforms or technologies.

PANELISTS:

Amy Bergeron, Director Manufacturing Technical Services, Alnylam Pharmaceuticals: Ms. Bergeron is currently the director of the MTS team at Alnylam Pharmaceuticals. Her team is responsible for overseeing the implementation and ongoing support of compliant cGMP processes at critical raw material, drug substance, and drug product manufacturing sites. She has been with Alnylam for just over 2 years.

Prior to joining Alnylam, Ms. Bergeron spent 5 years at Amgen working as both a Drug Product Team Lead, as well as a Principal Engineer in the Global Manufacturing Sciences and Technology group. Her responsibilities included leading the integration of contract manufacturing sites for in-house developed and acquired commercial products and directing a team of engineers providing technical support to multiple commercial contract manufacturers. Ms. Bergeron also spent 10 years at Wyeth Biotech, now Pfizer, in various drug product development and technology transfer roles supporting internal and external manufacturing of late stage clinical and commercial products. Prior to Wyeth, she spent 2 years at Biogen working on drug substance and drug product process development and technology transfer.

Outside of work, Ms. Bergeron serves as a member of the advisory board for the College of Engineering and Physical Sciences at the University of New Hampshire.
She holds an M.S. in Regulatory Affairs from Northeastern University, as well as both a B.S in Chemical Engineering and a B.S. in Biology from the University of New Hampshire.

Continue to next page…

Laura Adamson-Small, Director, Upstream Process Development, Homology Medicines: Laura Adamson-Small has been the Director of Upstream Process Development at Homology Medicines for the past 2 years, optimizing production platforms for adeno-associated viral vectors. Prior to joining Homology, she worked for the University of Florida Powell Gene Therapy Center optimizing production processes and analytical testing methods for viral vectors. Laura received her bachelor's degree in genetics from Iowa State University and Ph.D. in virology from the University of Florida.

John Batal, Director of Engineering, Nitto Avecia: For the past 10 years John has helped drive Avecia's growth in oligo manufacturing technology with new innovative solutions. He recently spoke at the 2018 TIDES Conference on the topic of process scaleup.

John began his career at Dow Chemical with 10 years in Process Development groups, including Dow's former Pharmaceutical business. He has an extensive background with innovative chemical process technologies, including 5 years developing efficient fuel cell systems with Arthur D. Little in Cambridge. In addition to oligonucleotide products, his pharmaceutical background includes 5 years with Acusphere as part of commercialization of their injectable microsphere product used in heart function diagnostics. He has 30 years of experience in process development, scale-up, and implementation of changes in regulated environments. John also has extensive background in chemical process safety.

H. Samantha Gao-Sheridan, Ph.D., Senior Director, Regulatory Affairs CMC, Alnylam: Dr. Gao-Sheridan is the Head and Senior Director of Regulatory Affairs CMC at Alnylam Pharmaceuticals, a company with a core focus in leading development of RNAi therapeutics toward genetically defined targets for the treatment of serious, life-threatening diseases.

Dr. Gao-Sheridan is a drug development and regulatory affairs professional with extensive experience providing leadership in developing innovative and compliant regulatory strategy in biologics and drugs for rare and unmet medical need programs. While having broad knowledge and experience in regulatory affairs overall, she specializes in CMC regulatory affairs and has led global regulatory CMC strategy development, regulatory agency interactions, submissions, registration, and post-approval life cycle management of a broad range of therapeutics, including monoclonal antibodies, fusion proteins, enzyme replacement therapies, drug-device combination products, peptides, and RNAi therapeutics. Dr. Gao-Sheridan is passionate about regulatory science and applying sound scientific approach to developing innovative regulatory solutions. She has participated and contributed in several industry organizations and working groups including PhRMA QbD Working Group, BIO Manufacturing, Quality, and Distribution Committee, and Oligonucleotide Safety Working Group.

Prior to joining Alnylam, Dr. Gao-Sheridan worked in Shire Pharmaceuticals, Wyeth Pharmaceuticals, and Vical Inc. She is a protein chemist and molecular biologist by training. She earned a B.S. in Medicine from Peking Union Medical College, M.S. in Toxicology from Rutgers University, and Ph.D. in Biochemistry and Molecular Biology from University of California, Irvine, followed by a post-doctoral fellowship in anthrax toxin research at Harvard Medical School.

MODERATOR:

Emily Airoldi, Senior Process Engineer, Wave Life Sciences Ltd.: Emily Davis Airoldi earned a Bachelor's (2005) and Master's (2007) degree in chemical engineering from the University of Massachusetts Lowell and most recently earned a Master's in Engineering Management from Tufts University, Gordon Institute (2018). Emily brings to this discussion 12+ years of experience as a process Engineer in the Biotech and Pharma industries. Emily has held process engineering roles in the Manufacturing Sciences and Technology (MSAT) organization at Genzyme Sanofi where she developed knowledge and expertise in biotechnology processes and cGMP manufacturing operations. She has also held Process Engineering and Project Engineering roles on Capital project teams at both Genzyme Sanofi and Shire where she led the design, installation, and verification of new manufacturing systems for commercial biologics cGMP production. Emily most recently Joined Wave Life sciences in 2017 as a Senior process engineer where she is leading the start-up and equipment technical support of downstream manufacturing systems in a new clinical manufacturing facility to produce oligonucleotide therapeutic candidates in support of clinical trials. In this role she has recently lead the development of the manufacturing system lifecycle program to be used at Wave Life Sciences for the design, installation and verification of manufacturing systems based on the application of concepts and best practices presented in ASTM E2500-07, ISPE, and PDA publications.

MEETING MANAGERS:

Janelle Carretero, New England Controls
Eric Felz, Shire

ISPE Boston Area Chapter Presents:

Pushing the Limits: Being Innovative in a Regulated Industry

Thursday, November 15, 2018

5:30 pm to 8:30 pm

ISPE Boston Area Chapter

Serving All of New England

THANK YOU TO OUR PROGRAM SPONSOR

CAI Commissioning Agents, Inc.

Alnylam

300 Third Street
Cambridge, MA 02142

PROGRAM SCHEDULE:

5:30 – 6:30 PM Registration, Reception and Networking Activity
6:30 – 8:30 PM Panel Discussion

REGISTRATION FEES:

		Registration by 11/8/2018	Registration After 11/8/2018
☐	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 8th ARE SUBJECT TO BILLING****

ISPE Boston Area Chapter Presents:

Pushing the Limits: Being Innovative in a Regulated Industry

Thursday, November 15, 2018

5:30 pm to 9:00 pm

Alnylam

300 Third Street
Cambridge, MA 02142

ISPE Boston Area Chapter

Serving All of New England

THANK YOU TO OUR PROGRAM SPONSOR

CAI Commissioning Agents, Inc.

DIRECTIONS:

Click here for door to door directions.

Please have a valid form of I. D. ready for a security checkpoint. Walk-ins are welcome to attend.

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

Parking garages in the area include Kendall Square South Garage ($10 if you enter after 4PM) and the Kendall Center Green Garage. Street parking is also available for a fee.