ISPE Boston Area Chapter Presents:

Process Simulation

Thursday, February 20, 2020

5:30 pm to 8:30 pm

CRB

101 Station Landing
Suite 210
Medford, MA 02155

ISPE Boston Area Chapter
Serving All of New England

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PROGRAM SUMMARY:

Simulation is a necessary and useful tool in the development of processes and equipment, particularly when full-scale testing is impractical or expensive. Process simulations in biopharma have evolved from the use of small- and lab-scale models, to electronic models (using Computational Fluid Dynamics and purpose-built process modeling software), and now to 3D printing to quickly develop and test physical models. In this session we will hear from speakers who have used various modeling techniques to develop and fine-tune biopharmaceutical processes and equipment.

**Please be advised that this program has a max capacity of 30 attendees.
Registrations will be taken on a first come, first serve basis.
Please contact the office at 781-647-4773 to be added to a waitlist.**

SPEAKERS:

Zheng Huang, Director Manufacturing Science Cell Culture and Bioprocess Engineering, Sanofi

Zheng Huang, Ph.D., has 17 years experiences in biopharma industry and instrumentation. At Sanofi, he is Director of Manufacturing Science Cell Culture and Bioprocess Engineering, part of Sanofi Biologics Global Manufacturing Science and Technology.

Zheng and his teams provide direct technical support to commercial cell culture operations at Sanofi and CMOs. He also leads MSAT Bioprocess Engineering function, an internal consulting group, to provide advanced data analytics, modeling, and pilot support to Sanofi Industry Affairs and R&D. He sponsors cross-functional Cell Culture simulator, Purification simulator, Computational Fluid Dynamics, Advanced Process Control, Machine Learning, and Process Raman teams in Sanofi biologics network.

Niranjan Kulkarni, Director, Operations Improvement, CRB Consulting Engineers

Niranjan Kulkarni, Ph.D., has over 15 years' experience in business process and data modeling, process simulations, operations improvements, layout optimizations and supply chain management. He has worked with pharmaceuticals, biotech, food, chemicals, semiconductor, electronics assembly & packaging, manufacturing and finance industries.

At CRB, he leads a team of engineers, using modeling and simulations and other AI techniques to improve client outcomes.

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PRESENTATION ABSTRACTS:

Implementation of Modeling Platform Approach to Accelerate Process Design and Product Launch
Zheng Huang, Director Manufacturing Science Cell Culture and Bioprocess Engineering, Sanofi
Modeling has been extensively used in the biopharmaceutical industry to support all stages of the product life cycle; this includes Discovery, Clinical, Process Development, Tech Transfer, to Commercial Manufacturing. In the era of digital transformation of pharmaceutical industry, individual models fuse into more powerful modeling platforms that play pivotal role in process design and product launch.

The presentation provides relevant case studies that highlight platform approaches from relatively simple cluster of models to more integrated platform. It starts with a simple case study, where Computational Fluid Dynamics, mass transfer model, and 3D-printed physical model were leveraged to answer practical questions during a tech transfer. Next, we discuss the integration of models into a powerful platform. The speaker will also share some perspectives on Digital Twin platform and potential applications in our industry.

Targeted audiences are engineers and scientists in the field of R&D, Manufacturing Technical Operations, and Quality, as well as any technical experts/consultants that support these functions.

Process Optimization and Simulation
Niranjan Kulkarni, Director, Operations Improvement, CRB Consulting Engineers
As many novel treatments move from development to commercialization, manufacturers are challenged to design and operate optimal facilities. Uncertainty in demands, ambiguity with new technology platform, variability due to raw material or manual operations, etc. add to the design challenge. Designing optimal facilities and production operations also has a significant impact on the Cost of Goods.

With improvement in computing power, Simulations and Artificial Intelligence (AI) techniques can be better employed to address the above-mentioned concerns. Computer modeling and simulations from an operational perspective can support the development of an optimal facility design along with developing operating strategies that will enable cell therapy manufacturers to meet the needs of patient populations, while better managing the Cost of Goods.

Learning Objectives (3):
- Learn how to improve facility design using operational models and computer simulations
- Understand how machine learning using neural networks, a technique within the AI domain, can be used to better estimate machine reliability
- Learn how to maintain these models as the process matures

MEETING MANAGER:

Chris Ciampa, CAI
Aaron Hubbell, Delta Project Management

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PROGRAM SCHEDULE:

Registration and Reception:	5:30 – 6:30 pm
Introductions:	6:30 – 6:40 pm
Presentations + Q&A:	6:40 – 8:30 pm

REGISTRATION FEES:

	Registration by 2/13/2020	Registration After 2/13/2020
☐ 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: _____

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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 February 13th ARE SUBJECT TO BILLING****

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DIRECTIONS AND PARKING:

Click here for door to door directions.