

ISPE Boston Area Chapter Presents:

PANEL DISCUSSION

Virtual Utilization in the Pharma/Biotech Industry:

Remote Solutions for Training, Factory Acceptance Testing (FAT), and Auditing

Wednesday, June 23, 2021

5:00 PM – 7:30 PM EST

Cross Insurance Pavilion

Located at Gillette Stadium, Foxborough, MA



Serving All of New England

PROGRAM SUMMARY:

Virtualization has become a critical communication tool during the pandemic. As a result of public safety requirements, the biopharmaceutical industry has had to adjust by adopting virtual technologies and applications to continue making life saving medicines. This hybrid event will include 3 mini presentations that have been utilized during the pandemic, followed by a panel discussion where we will discuss virtualization in the post-pandemic era.

- **Topic 1- Training:** Integrated cloud-based virtual laboratories have allowed learners to perform authentic workplace tasks online, using highly accurate digital copies of real laboratory and industrial scale biomanufacturing equipment. During this presentation we will model Advanced tools for e-learning that can be utilized for training purposes whether it's for new hires, annual training, cross-training, or other.
- **Topic 2- FATs:** During this presentation we will address the pros and cons of virtual FATs, virtual tools to optimize success, and lessons learned.
- **Topic 3- Auditing:** During this presentation we will discuss the advantages and opportunities of performing remote audits for third-party vendors and discuss the tools and policies to ensure a successful remote audit. Discuss a risk-based approach to determine the usage of remote access to manage CMO activities during manufacturing operations.

PROGRAM SPONSORS:



WHO SHOULD ATTEND THIS WEBINAR:

This program is geared towards professionals and managers interested in virtual utilization in the pharma/biotech industry.

PANELISTS:

Yakov Cherner, President, Advanced Tools for e-Learning (ATeL)



Dr. Yakov E. Cherner is the Founder and President of the Massachusetts-based company ATeL-Advanced Tools for e-Learning, which has been developing cloud-based, highly interactive, and customizable online learning activities, virtual laboratories, and entire e-learning solutions for various areas of STEM education and for professional training. Dr. Cherner proposed and implemented the pioneering concept of integrated and adaptable gamified e-learning modules that incorporate synchronized and interconnected simulations, virtual reality (VR), augmented reality (AR), and physical equipment. This combination has proven to be incredibly engaging and meaningful for digital-native students and workers.

ATeL's educational and training tools are widely used in academics, military, and industry in the US and abroad for preparing students and trainees for efficient hands-on on-site practice, accelerating the development of operational, maintenance and troubleshooting skills, as well as deepening learners' conceptual understanding.

Dr. Cherner holds a Ph.D. in Physics and Material sciences. He was a Director and Principal Investigator for 12+ educational R&D awards and projects funded by the National Science Foundation. He has also published over 100 papers in national and international journals and made dozens of presentations at various conferences.

Rusty Morrison, Director of Operations – Northeast, CAI



Rusty Morrison is an experienced pharmaceutical professional with 35 consecutive years of experience at all levels in commissioning, qualification, validation, technology transfer, engineering, and manufacturing. In his current role as Director of Operations for the Northeast, he is responsible for successful project delivery for CAI's team of 45+ agents who are helping clients produce life-saving medicines.

Paul Partovi, Associate Director of Quality Assurance, Sanofi



Paul Partovi has over 20 years of experience in the biopharmaceutical industry. Paul graduated with a Bachelor of Science in Microbiology from the California State University of Long Beach and has a Master of Liberal Arts in the Field of Management from Harvard. Paul started his career as a quality control Microbiologist at Baxter supporting recombinant factor VIII and Small Pox vaccine manufacturing operations. Paul Continued his Career at Amgen as a microbiologist and then transitioned into a Quality Assurance role supporting the manufacturing and release of Enbrel. At Alkermes, Paul worked on small molecule projects for Inhaled Insulin system, before moving on to his current Role. Currently, Paul has a leadership role in overseeing the Quality aspects of upstream, downstream, and Final Filling for the clinical manufacturing operations At Sanofi. Also, he is responsible for quality oversight of new drug development processes. As a certified Quality auditor, part of his job entails auditing contract laboratory and manufacturing facilities. His goal is to bring the industry into the classroom and transfer classroom learning to real-world applications.

Sunny Tam, PhD, Director of Professional Science Master's Program in Biotechnology, Framingham State University



Sunny Tam, PhD has 20 years of biotechnology and academic experiences in early stage R&D, preclinical testing, assay and technology development following his training from the Harvard University School of Public Health. He has held numerous scientific and management positions in small molecule discovery and protein therapeutic companies including Mitotix, Inc., Texas Biotechnology Corporation and Tanox Inc. Dr. Tam is a pioneer in protein microarray development and application of proteomic tools in drug discovery, biomarker discovery and assay development. He is well published and has contributed significantly toward a number of issued patents and federally awarded grants. During his tenure as Program Director at Charles River Laboratories and then University of Massachusetts Medical School, Dr. Tam successfully completed numerous projects for major US biopharmaceutical and government sponsors in new protein technology development, further advancing biomarker discovery and product applications in a number of chronic human diseases. More recently serving as the VP of R&D at Nuclea Bio, he has built a GLP facility for the development of FDA regulated clinical diagnostic assays with novel biomarkers. At Clark University as a Research Associate Professor, he has established a state of art Proteomic and Metabolomic laboratory for internal research and student teaching. Currently, he is the Director of the Professional Science Master's (PSM) program in Biotechnology at Framingham State University.

EVENT AGENDA:

- 5:00 pm – 6:00 pm – Registration & Networking Reception
- 6:00 pm – 7:00 pm – Panel Discussion & Presentations
- 7:00 pm – 7:30 pm – Audience Q+A
- 7:30 pm and on – All attendees are welcome to stay and attend the New England Revolution soccer game against the New York Red Bulls at Gillette Stadium for FREE

MEETING MANAGER:

Shannon DeMello, CAI

REGISTRATION CAPACITY:

Please note that this event is limited to only 50 attendees and will be first come, first served! If you want to register, please do so as soon as possible. The ISPE Boston office cannot hold spaces.

REGISTRATION FEES:

	Registration by 6/9/2021	Registration After 6/9/2021
<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Emerging Leaders Members	\$20	\$30
<input type="checkbox"/> Nonmembers	\$95	\$115
<input type="checkbox"/> Student Members	FREE	FREE

DIRECTIONS AND PARKING:

[Click here](#) for door to door directions. Parking information will be shared in your pre-event confirmation email.

ONSITE MASK & SOCIAL DISTANCE POLICY:

The ISPE Boston Area Chapter is following both state and event venue COVID guidelines. Attendees will be required to wear a face mask while inside the event venue, unless you are seated at your table. As of May 11th, food and beverages will have to be delivered by Gillette staff to each attendee (no buffet, bar, or passed food permitted). We will update this section if that changes. Outside, attendees may remove masks so long as they can remain 6' away from each other. Gillette Stadium security staff will be monitoring for compliance.

****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER June 15, 2021 ARE SUBJECT TO BILLING****

REGISTRATION IS NOW OPEN ONLINE!

Please complete the online registration at www.ISPEBoston.org/Events.

Pay by credit card OR check.