ISPE Boston Area Chapter's Fall Education Summit

OCTOBER 2020

Schedule-At-A-Glance

27	28	29	30	1	2	3
				Welcome Email - Attendees receive their login instructions!		
WEEK 1 / TRACK 1: RISK MANAGEMENT - Thank You to This Week's Gold Track Sponsor NECI						
4	5	6	7	8	9	10
	12:00 PM - WELCOME *What's coming up this week*	**11:00 AM - EDUCATION SESSION** *Emerging Technologies in Pharmaceutical Water Systems* by Nissan Cohen & Michael Rodionov **1:00 PM - EDUCATION SESSION** *Resiliency, Redundancy, and Sustainability: How to think about resiliency, redundancy, and sustainability in lab design for a leased portfolio* by Robin Dorogusker & Maureen McCaffrey **3:00 PM - EDUCATION SESSION** *Business Continuity and Resiliency: What role do we play in planning for our future?* by John Cunningham	**12:00 PM - PROFESSIONAL DEVELOPMENT SESSION** *Careers in Novel Therapies: A Discussion for Managers and Candidates* Moderated by Laura Berberian & Jesse McLaughlin Panelists: Eliana Clark; Marika St. Amand; Mike Wourms	**9:00 AM - EDUCATION SESSION** *Utilization of the Risk Based Approach to Confirm the Quality, Safety & Efficacy Attributes of the ATMPs and Compliance with cGMP* by Francesca McBride **12:00 PM - EDUCATION SESSION** *How Pharma Can Identify Tax Incentives & Stop Leaving Money on the Table* by Lynn Tokarczyk **3:00 PM - TRACK PANEL DISCUSSION** *Moderated by Aaron Hubbell*		
WEEK 2 / TRACK 2: ATMP - Thank You to This Week's Gold Track Sponsor BOSTON ANALYTICAL						
11	12	13	14	15	16	17
		3:00 PM - EDUCATION SESSION *Flexible Gene Therapy Facilities - Current Best Practices* by Ankur Shah	**12:00 PM - PROFESSIONAL DEVELOPMENT SESSION** *Preparing Our Workforce for C&GT Manufacturing* by Richard Tree	**9:00 AM - EDUCATION SESSION** *Viral Safety of Cleaned Surfaces Using a Risk-Based Approach* by Paul Lopolito **12:00 PM - EDUCATION SESSION** *Countdown to Thaw: Successfully Building a Cell Therapy Clinical Manufacturing Facility from the Ground Up in Less than 1 Year* by Michael Cody & Brian Feeney **3:00 PM - TRACK PANEL DISCUSSION** *Moderated by Aaron Hubbell*	**1:00 PM - EDUCATION SESSION** *Manufacturing Facility Design Considerations for ATMPs* by Charles Heffernan & Emily Thompson	
WEEK 3 / TRACK 3: Facilities of the Future - Thank You to This Week's Gold Track Sponsor BURKERT						
18	19	20	21	22	23	24
	10:00 AM - SPONSORED EDUCATION SESSION *Assuring Product Quality and Environmental Safety through the Drug Life Cycle - Are you using a Risk-Based Approach?* by Ernest Fung, Heather Lynch, Andy Maier & Ania Urban **Sponsored by CardnoChemrisk**	**11:00 AM - EDUCATION SESSION** *Death to Welding (Analysis on High Throughput Closed Processing Strategies for Gene Therapy Manufacturing)* by Robert Hendrix **3:00 PM - EDUCATION SESSION** *LCA Insights into Single-Use Biomanufacturing Stability* by Bill Whitford	**TIME TBD - YOUNG PROFESSIONALS PROGRAM** *TBD* **6:30 PM - VIRTUAL NETWORKING** *Happy Hour Networking Mixer* Hosted by the Membership Committee	**9:00 AM - EDUCATION SESSION** *Cold Water for Injection Generation & Distribution* by Annelie King **12:00 PM - EDUCATION SESSION** *Multi-Modal Facilities: Delivering Flexible, Future-Proof ATMP Facilities* by Brita Salzmann & Grace Linton **3:00 PM - TRACK PANEL DISCUSSION** *Moderated by Jim Grunwald*		
WEEK 4 / TRACK 4: Pharma 4.0 - Thank You to This Week's Gold Track Sponsor MASY BIOSERVICES						
25	26	27	28	29	30	31
		11:00 AM - EDUCATION SESSION *Validation 4.0: Opportunities, Challenges, and Paradigm Shifts in a Pharma 4.0 World* by Chip Bennett **3:00 PM - EDUCATION SESSION** *Risk Mitigation for Higher Levels of Data Integrity* by Rick Jarrell	**4:00 PM - WOMEN IN PHARMA SESSION** *Implicit Bias—Actions for Change* by Fauzia Amuda & Joanne Kamens, PhD	**9:00 AM - EDUCATION SESSION** *Keeping Pace with the Speed of Innovation: Facility Optimization through Construction Tech* by Amr Raafat & Bill Olsen **12:00 PM - EDUCATION SESSION** *How Digitalization Can Help Fast-Track Early Development to Manufacturing* by Martin Mayer **3:00 PM - TRACK PANEL DISCUSSION** *Moderated by Darin Ellingson*	**TIME TBD - MEET THE BOARD** Town Hall Style Q&A and Networking Event	

SCHEDULE-AT-A-GLANCE

WEEK 1 / Track 1: Risk Management

Tuesday, October 6 11:00 am – 12:00 pm	***Emerging Technologies in Pharmaceutical Water Systems*** Presented by: Nissan Cohen, President, Biopharmaceutical Water Doc & Michael Rodionov, Principal Engineer, MMR Consulting
Tuesday, October 6 3:00 pm – 4:00 pm	***Developing a Cyber-Resilient Production Environment Using IT, OT and Security Team*** Presented by: John Cunningham, Director & Industrial IT, RoviSys
Thursday, October 8 9:00 am – 10:00 am	***Utilization of the Risk Based Approach to Confirm the Quality, Safety and Efficacy Attributes of the ATMPs and Compliance with cGMP*** Presented by: Francesca McBridge, Regulatory Specialist Director, Jacobs & Todd Rumsey, Process SME, Jacobs
Thursday, October 8 12:00 pm – 1:00 pm	***How Pharma Can Identify Tax Incentives & Stop Leaving Money on the Table*** Presented by: Lynn Tokarczyk, Government Tax Incentives Consultant & President, Business Development Strategies, Inc.

WEEK 2 / Track 2: Advanced Therapy Medicinal Product (ATMP)

Tuesday, October 13 11:00 am – 12:00 pm	***Session Info Coming Soon!***
Tuesday, October 13 3:00 pm – 4:00 pm	***Flexible Gene Therapy Facilities - Current Best Practices*** Presented by: Ankur Shah, Senior Process Engineer, DPS Group
Thursday, October 15 9:00 am – 10:00 am	***Viral Safety of Cleaned Surfaces Using a Risk-Based Approach*** Presented by: Paul Lopolito, Technical Services Senior Manager, STERIS Corporation
Thursday, October 15 12:00 pm – 1:00 pm	***Countdown to Thaw: Successfully Building a Cell Therapy Clinical Manufacturing Facility from the Ground Up in Less than 1 Year*** Presented by: Michael Cody, Senior Solution Architect, NECI & Brian Feeney, Associate Director of Manufacturing Engineering, Rubius

WEEK 3 / Track 3: Facilities of the Future

Tuesday, October 20 11:00 am – 12:00 pm	***Death to Welding (Analysis on High Throughput Closed Processing Strategies for Gene Therapy Manufacturing)*** Presented by: Robert Hendrix, Process Engineer III, Thermo Fischer Viral Vector Services
Tuesday, October 20 3:00 pm – 4:00 pm	***Recycling Options for Single Use Facilities*** Presented by Bill Whitford, Life Science Strategic Solutions Leader, DPS
Thursday, October 22 9:00 am – 10:00 am	***Cold Water for Injection Generation & Distribution*** Presented by: Annelie King, PMP, Projects Manager, BWT Pharma & Biotech Inc.
Thursday, October 22 12:00 pm – 1:00 pm	***Multi-Modal Facilities: Delivering Flexible, Future-Proof ATMP Facilities*** Presented by: Brita Salzman, Process Engineer, CRB and Grace Linton, RA, AIA, LEED AP BD+C, Process Architect, CRB

WEEK 4 / Track 4: Pharma 4.0

Tuesday, October 27 11:00 am – 12:00 pm	***Validation 4.0: Opportunities, Challenges, and Paradigm Shifts in a Pharma 4.0 World*** Presented by: Chip Bennett, Assistant Director of Global C&Q, Commissioning Agents, Inc. (CAI)
Tuesday, October 27 3:00 pm – 4:00 pm	***Risk Mitigation for Higher Levels of Data Integrity*** Presented by: Rick Jarrell, Business Development Manager - Life Sciences, Eurotherm by Schneider Electric
Thursday, October 29 9:00 am – 10:00 am	***Keeping Pace with the Speed of Innovation: Facility Optimization through Construction Tech*** Presented by: Amr Raafat, Vice President of VDC and Technology, Windover
Thursday, October 29 12:00 pm – 1:00 pm	***How Digitalization Can Help Fast-Track Early Development to Manufacturing*** Presented by: Martin Mayer, Business Development - Smart Engineering Services, ZETA GmbH

DETAILED EVENT INFO - EDUCATION

WEEK 1 / Track 1: Risk Management

Tuesday, October 6 11:00 am – 12:00 pm	***Emerging Technologies in Pharmaceutical Water Systems*** Presented by: Nissan Cohen, President, Biopharmaceutical Water Doc & Michael Rodionov, Principal Engineer, MMR Consulting This presentation will primarily focus on two emerging technologies; (1) Membrane-WFI systems, as well as (2) Ozone-Sanitized WFI Distribution Loops. Membrane-WFI Generation: • Review various generation methods; Multi-Effect Stills, Vapour Compression Stills and Membrane WFI Technology • Review PROs and CONs and risks between various technologies • Review when it may make sense for utilities to utilize one technology over another, i.e. • Small WFI Still, with small occasional usage might be Multi-Effect due to reduced CAPEX and Multi-Effect Still (MES) does not require to continuously operate • VC Technology is great for flexibility between Hot and Cold, however it uses more power than Membrane WFI • Membrane WFI Technology is great for Cold/Ambient only applications, however it requires more maintenance than VC Stills • Actual technology selection depends on central clean utilities plant consumption, redundancy, temperatures, excess capacity requirements etc. There is no “industry best” solution, it’s always a case by case scenario. • Review case studies Discuss use of Ozone in WFI Distribution Loops Use of Ozone in Distribution Loops: • Review conventional use of Ozone in PW Loops • Discuss Corona Discharge Ozone Generators widely used in the industry • Discuss potential issues with utilization of Corona Discharge in WFI • Discuss other types of Ozone Generators (i.e. electrolytic); review pros/cons/capex and opex costs of Electrolytic, and why electrolytic might be more suitable if used for WFI • If WFI Loop is designed with Electrolytic Ozone • This is not currently a practice in North America, but is a practice within the industry in Europe • Design considerations for WFI; i.e. Ozone Levels during recirc, Ozone levels during sanitization, sanitization of POUs, and use of Electrolytic Ozone Generators. • Review lessons learned / case studies

Tuesday, October 6 3:00 pm – 4:00 pm	***Developing a Cyber-Resilient Production Environment Using IT, OT and Security Team*** Presented by: John Cunningham, Director & Industrial IT, RoviSys As life science production processes become more connected than ever the risk of major disruptions to production also escalates. Acts of nature and cyber attacks can halt production and result in extended downtime and lost revenues. A comprehensive cyber resilient strategy is needed to preemptively prepare for these types of event. A comprehensive strategy requires the input of IT, manufacturing, and the corporate security team to assure a plan that is workable, effective, and fits within budget constraints. This session addresses the factors to consider in designing and implementing a cyber resiliency strategy. We discuss building the resiliency team, identifying and assessing vulnerabilities and risks, and methods for implementing the plan. This session is intended for management, IT and security personnel who are tasked with protecting production facilities, and production personnel who will be impacted by cybersecurity in the production facility. Attendees will gain the following from this session: • What cyber resiliency is and why it is important for life science manufacturers • How to define and develop a cyber resiliency plan • Who to include on the cyber resiliency team
Thursday, October 8 9:00 am – 10:00 am	***Utilization of the Risk Based Approach to Confirm the Quality, Safety and Efficacy Attributes of the ATMPs and Compliance with cGMP*** Presented by: Francesca McBride, Regulatory Specialist Director, Jacobs & Todd Rumsey, Process SME, Jacobs The international regulatory agencies continue to place an increased expectation that a risk-based approach will be utilized to confirm that the quality, safety and efficacy attributes of ATMPs and compliance with cGMP is ensured, regardless of where they are developed. The risk-based approach enables the manufacturer to design the process operations, technical and mechanical measures that are put in place to comply with cGMP and to ensure quality based on the specific risks of the product and manufacturing process. For autologous cell therapy facilities that will support the manufacture of multiple products, consideration must be given to the application of control strategies to ensure the quality, safety and efficacy of the products are maintained. The control strategies cover various aspects including but not limited to: 1. Microbial contamination control 2. Viral/viral vector contamination control 3. Cell material chain of identity / custody controls 4. Raw material/consumable controls 5. Product and process control strategy The controls include segregation and cross contamination prevention elements associated with either facility layout/design, engineering/automation systems or procedural controls. A quality risk assessment that evaluates risk to the product based on a review of the process operations and control strategies should be performed.

	Objectives: This presentation will review the tools, strategy and rationale for the execution of a risk-based assessment for an autologous cell therapy facility: • Review the strategy, goals and purpose of the RA • Define the process and support operations performed in facility • Review an overall facility layout and classification • Present a risk assessment that addresses: Microbial contamination, Viral/viral vector contamination, Flows of people, product, equipment and waste through the facility, Segregation of product and operations. Take Home Benefits: • Increased knowledge and understanding of the risk-based strategy execution to confirm that the facility design and implemented operational controls ensure the required quality, safety and efficacy attributes for the manufacture of cell therapy products.
Thursday, October 8 12:00 pm – 1:00 pm	***How Pharma Can Identify Tax Incentives & Stop Leaving Money on the Table*** Presented by: Lynn Tokarczyk, Government Tax Incentives Consultant & President, Business Development Strategies, Inc. Too many life science companies considering setting up shop in Massachusetts or relocating/expanding within the Commonwealth are missing out on potential savings by not taking advantage of local and state tax incentives. With new life science companies flocking to the Boston area and existing companies experiencing unprecedented rapid growth, companies are looking at costly building renovation and construction projects all around the Commonwealth, with some organizations requiring expansion less than a year after initially finding space. It is imperative that decision-makers understand the importance of identifying tax incentives that help businesses make corporate real estate decisions and save thousands - if not millions - of dollars long before shovels go into the ground. Municipalities are eager to work with companies bringing jobs and investment to their communities, but companies often don't know where to look or how to obtain the tax incentives that will make these projects economically viable. This presentation will focus on: • Identifying different kinds of tax incentives (State Tax Credits, State Abandoned Building Tax Deduction, Municipal Tax Increment Financing, Municipal Personal Property Tax Relief) • How to Negotiate Incentives (organizations require experienced consultants with diplomatic negotiating skills who understand the complexities of the state and local political landscape) • How to Navigate the Municipal Approval Process (how to sell the project to local officials, community leaders, and Town Meeting) Leading life science companies have taken advantage of these tax incentives and can be used as case studies that illustrate how the process works successfully when considering locating or expanding in Massachusetts. This presentation will be unique

	among other submissions and presents an opportunity for ISPE to diversify its programming in a relevant way.

WEEK 2 / Track 2: Advanced Therapy Medicinal Product (ATMP)

Tuesday, October 13 11:00 am – 12:00 pm	***Session will be announced soon!***
Tuesday, October 13 3:00 pm – 4:00 pm	***Flexible Gene Therapy Facilities - Current Best Practices*** Presented by: Ankur Shah, Sr. Process Engineer, DPS Group Given the rapid increase in the number of companies with gene therapy products in the clinic and those transitioning through to commercial manufacturing, the demand for appropriately designed facilities is also increasing. As cell and gene therapy developers progress through the clinical trial phases to commercial manufacture, the strain on the production process increases, testing the limits of scalability and robustness. During these stages additional capacity may be required to transition through clinical trials and move to commercial manufacture, which may result in the need to move to a new facility or invest in a build program. Many companies have engaged in facility design projects to provide in house capability for late stage clinical and commercial launch facilities. The objectives of the presentation is to share experiences in facility design concepts for current generation gene therapy facilities based on a number of case studies from projects over the last 3 years. Gene therapy manufacturing facilities, by the nature of the process, have inherently different challenges to the more traditional bulk biologics, Mabs based, facilities. Given that we are designing facilities for processes that are still in development, we have to translate a development scale process to a scalable and robust cGMP process. Manufacturing processes that involve the replication of a virus present challenges with respect to facility design and equipment selection. More controls are therefore required to segregate and contain these process streams from other parts of the manufacturing plant, which is a key requirement. The understanding of the process and the scalability challenges have to be considered when designing a facility to manufacture the appropriate number of doses for the forecast market requirements. The engineering design team has to work closely with the development and scale up team to understand the process limitations and the limiting steps while defining the maximum batch scale to provide the forecasted market requirements. Our presentation will inform the audience of the typical design process undertaken to achieve the optimal outcome within the limits of scale and project budget. We review the process flow mapping, the process modelling to inform the optimal combination of seed and production bioreactors and downstream processing trains and use of buffers and utilities. We discuss the cGMP requirements and ensuring regulatory guidance is considered for containment, prevention of cross contamination, protecting the product and the manufacturing personnel. The presentation will elaborate on the segregation strategy for higher risk process steps, host cell infection, viral production, purification and product formulation in order to contain vector particles within a specified zone in the facility. We discuss the typical equipment available and challenges and developments. The audience will leave with an excellent understanding of typical design concepts, limitations and opportunities.

Thursday, October 15 9:00 am – 10:00 am	***Viral Safety of Cleaned Surfaces Using a Risk-Based Approach*** Presented by: Paul Lopolito, Technical Services Senior Manager, STERIS Corporation Viral cross-contamination of process equipment and small parts is a concern for cell therapy, biopharmaceutical and medical device industries. Viral contamination can lead to costly delays in production, product loss, and regulatory issues. Viral clearance studies focus on viral inactivation or removal steps within the process flow ensuring a theoretical viral log reduction and low viral risk of the product. The viral clearance strategy often overlooks the potential of cross-contamination from equipment surfaces and small parts from one donor, batch or product to another. An effective clean-in-place (CIP), automated parts washer cycle, or manual cleaning procedure incorporating an alkaline detergent can help mitigate the risk of cross-contamination. Understanding critical cleaning parameters and viral inactivation parameters is paramount in assessing viral safety of cleaned surfaces. The presentation includes a review of published viral inactivation data using alkaline detergents at various temperatures as well as presenting unpublished data on a chlorine containing alkaline detergent. Depending on the assessed risk, cleaning procedures can be modified to address viral safety and segregation practices of automated cleaning of small parts pre and post viral clearance may be relaxed or eliminated.
Thursday, October 15 12:00 pm – 1:00 pm	***Countdown to Thaw: Successfully Building a Cell Therapy Clinical Manufacturing Facility from the Ground Up in Less than 1 Year*** Presented by: Michael Cody, Senior Solution Architect, NECI & Brian Feeney, Associate Director of Manufacturing Engineering, Rubius At the end of 2018, Rubius Therapeutics set an audacious goal: to achieve internal clinical manufacturing capability for its novel Red Platform by the end of 2019. Over the course of the following year, the project went through all phases of a standard capital project at an accelerated pace. From conceptual design, vendor selections, construction, and technology deployment, the Rubius team and their vendor partners were able to deliver the project at breakneck speed. This presentation will share the perspectives of several project team members regarding what was learned and accomplished by going through the project. By attending the session you will learn: • How the team planned and successfully achieved an aggressive project timeline. • The capital programs challenges that were experienced in the fast deployment, and how they were solved. • The outcomes and takeaways from going through the fastest project deployment the team members have ever been involved with.

WEEK 3 / Track 3: Facilities of the Future

Tuesday, October 20 11:00 am – 12:00 pm	***Death to Welding (Analysis on High Throughput Closed Processing Strategies for Gene Therapy Manufacturing)*** Presented by: Robert Hendrix, Process Engineer III, Thermo Fischer Viral Vector Services High-throughput manufacturing for cell and gene therapy processes present multiple time in motion challenges which must be optimized to allow for high throughput Stage 3 and commercial scale processing. The following presentation shall highlight these challenges and evaluate them against traditional single use design and manufacturing and supply chain approaches and propose alternative solutions which intern de-bottleneck and allow for cell and gene therapy high throughput manufacturing while minimizing overall costs. This session is geared toward: • Industry professionals interested in evaluation of manufacturing strategies for high throughput cell and gene therapy process. With approaches geared toward consistent processing and scale-up for facilities designed for upward of 300 batches of throughput per calendar year. • Industry professionals interested in design of facilities geared toward high-throughput manufacturing for cell and gene therapy
Tuesday, October 20 3:00 pm – 4:00 pm	***Recycling Options for Single-use Biomanufacturing Materials*** Presented by: Bill Whitford, Life Science Strategic Solutions Leader, DPS The biotechnology community is concerned about the environmental burden of the single-use materials used in biomanufacturing. In designing sustainable manufacturing systems, it is important to consider all relevant types and sources of environmental stress. Life Cycle Assessment (LCA) is a science-based approach for evaluating the environmental impacts, benefits, trade-offs or burden shifts of a process. LCA teaches us that disposal of the used plastic biomanufacturing materials actually contributes a very small percentage of the overall environmental burden. Nevertheless, we are concerned about what to do with all of that used plastic. Options available for the post-use handling of manufacturing plastics include the currently popular approaches of sending it to a landfill or non-functional incineration. However, technology exists to "recycle" it through a number of means. We can now use the entire object itself again in the same or less-stringent application, recover the object's stored energy by direct incineration for power generation, use pyrolysis to produce a complex liquid mixture for such things as fuel, or reuse the cast plastic polymer in its original state for producing such lower stringency products as lumber or roads. Furthermore, technologies exist to support liquefying the plastic polymer and employing that in a new product, de-polymerizing the constituent polymer and re-polymerizing as virgin plastic resin, or even breaking the plastic monomer down to its constituent simple chemicals for use in producing virgin plastic monomer. Advantages and disadvantages of these approaches will be discussed.

Thursday, October 22 9:00 am – 10:00 am	***Cold Water for Injection Generation & Distribution*** Presented by: Annelie King, PMP, Projects Manager, BWT Pharma & Biotech Inc. Changes in the Pharmaceutical & Biotech market drives changes focusing on flexibility, lower cost and less infrastructure. Since the Ph EUR allowed WFI to be produced by a "purification process equivalent to distillation" in April 2017 the interest to use ambient WFI has increased. This presentation shows benefits and purpose together with a PQ Case Study of an Ambient system.
Thursday, October 22 12:00 pm – 1:00 pm	***Multi-Modal Facilities: Delivering Flexible, Future-Proof ATMP Facilities*** Presented by: Brita Salzman, Process Engineer, CRB and Grace Linton, RA, AIA, LEED AP BD+C, Process Architect, CRB Between newly developed products, strategic partnerships, and acquisitions in the Advanced Therapy Medicinal (ATMP) market, companies are racing to find or create capacity for plasmids, viral vectors, gene modified cell therapies, and fill finish products. Owner companies and entrepreneurs are considering building multi-product or multi-modal ATMP facilities to meet this emerging demand. They are also looking at how to "future proof" their investment so that it works for next generation manufacturing processes. A dedicated manufacturing facility can be costly, and limits options for the future. Why not have a facility that can produce multiple product types and allows for adaptability to an evolving product pipeline? Attendees will learn: • What the future of the "flexible facility" truly looks like for companies with multi-product types • How to reduce the risk of cross-contamination in a multi-product facility • How to "future proof" your design to leverage developments in closed and automated processing • How to scale appropriately to achieve faster speed-to-market, lower costs and ultimate manufacturing flexibility A case study demonstrating how these concepts are put into practice will be outlined as a learning tool for attendees to grasp real-time challenges and opportunities in designing ATMP facilities.

WEEK 4 / Track 4: Pharma 4.0

Tuesday, October 27 11:00 am – 12:00 pm	***Validation 4.0: Opportunities, Challenges, and Paradigm Shifts in a Pharma 4.0 World*** Presented by: Chip Bennett, Assistant Director of Global C&Q, Commissioning Agents, Inc. (CAI) As Pharma 4.0 increasingly becomes reality, our validation practices must change. We can no longer apply 20th century thinking to 21st century technology and resources. Validation must adapt to industry shifts from iterative to disruptive innovation, from batch to continuous processing, from bulk processing to personalized medicine, from centralized systems to the Internet of Things (IoT), from controlled data to distributed data, and similar changes. This session will discuss the challenges, and also the opportunities, for our industry in addressing these paradigm shifts.
Tuesday, October 27 3:00 pm – 4:00 pm	***Risk Mitigation for Higher Levels of Data Integrity*** Presented by: Rick Jarrell, Business Development Manager - Life Sciences, Eurotherm by Schneider Electric Data Integrity should be of paramount concern for all pharmaceutical and biotechnology manufacturers. The risk of having bad data is high, and the result can be a significant financial risk to a business, if not a suspension of operations. 1. The adoption of ALCOA+ guidelines for the preservation of data can offer significant risk reduction 2. Digitizing processes can also reduce risk 3. It is critical that business systems and standard operating procedures are tested and proven. 4. Data Integrity risk can be reduced by the proper selection of solution providers that understand Data Integrity obstacles. 5. Attention to internal and external data security is also of major concern. 6. We can also reduce risk associated with the human factor by continuing to increase our employees knowledge base. This session will be geared towards pharmaceutical and biotechnology manufacturers operating cGMP environments who might be struggling with the risks associated with accumulating low integrity data from their processes.

Thursday, October 29 9:00 am – 10:00 am	***Keeping Pace with the Speed of Innovation: Facility Optimization through Construction Tech*** Presented by: Amr Raafat, Vice President of VDC and Technology, Windover Construction and Bill Olsen, VP of Construction Operations, Windover Construction Evolving and adapting your facility to keep pace with the brilliant innovation occurring within its walls is mission critical. But what happens if your organization is challenged by lack of time, resources, and capital to dedicate to this purpose? The road to innovation does not have to stop there. With today's emerging construction technologies, Building Information Modeling (BIM), Reality Capture, Digital Fabrication, and Robotics, the design, construction, and maintenance of your life science facilities is made easier than ever. Construction technologies like these are optimizing facility management and paving the way for even greater life science innovation. This presentation will explore these construction technologies and how their application makes facility management a more collaborative, economical, and efficient process. Examples taken from recent life science projects will be shared to demonstrate the versatile applications of these technologies, including a hands-on mixed-reality demonstration. Attendees will leave with a greater understanding of the broad spectrum of technologies available to them and how they can be leveraged during different phases of a construction project to enable a user-friendly facilities maintenance asset for the future of their facility. 1. Learn about the latest construction technology tools available to you including Building Information Modeling (BIM), Reality Capture, Digital Fabrication, and Robotics that are optimizing the development, construction, and maintenance of life science facilities. 2. Understand how to minimize your risk and enhance quality when it comes to your facility design, construction, and maintenance through the use of technology and digital facility maintenance platforms. 3. Experience a live, mixed-reality demonstration with the Microsoft HoloLens to experience firsthand how emerging technologies, like the HoloLens, simplify the facility design and development process."
Thursday, October 29 12:00 pm – 1:00 pm	***How Digitalization Can Help Fast-Track Early Development to Manufacturing*** Presented by: Martin Mayer, Business Development - Smart Engineering Services, ZETA GmbH "Agility, flexibility and adaptability" caused by business drivers such as reduced time-to-market, personalized medicine, improved cost effectiveness and "best-in-class" competitiveness are among the most important subjects in the biopharma industry today. In parallel, digitalization and trends like Industry 4.0, IoT etc. have created new developments and technologies where machine learning and Artificial Intelligence (AI) are currently seen as one of the hottest topics. A key challenge of companies engaged in drug development is how to accelerate the process from the clinical stage to commercial manufacturing scale. Leveraging the digital twin can be a powerful tool, for accelerating this process, by combining the different build-outs - from early development to final start-up - of the manufacturing plant.

	As a result, it is possible to simultaneously develop and optimize the product or process and derive valuable information for engineering the scale-up (pilot scale) and the final plant. This concurrent engineering leads to reduced time, earlier market entry and increased competitiveness of commercial production. A number of innovative and revolutionary applications powered by digitalization are (suddenly) just around the corner: • Model-based process development • Intensified DOE • GMP ready SKID development in early stage (hygienic design, data integrity) • Scale-up based on digital twins of process and equipment (CFD simulation) • Operator training (Virtual Reality/Augmented Reality) • Start-up training and operator training simulation (VR/AR) • Changeover strategies based on process models Learnings: 1. How to categorize digital twin applications, a structure and categorization approach is presented to find the way through digital twin applications. The introduction of digital twins for plant, process, product and patient will be discussed. 2. How modern workflows in engineering can contribute to a digital representation of a plant to be built. How aspects from multiple disciplines are orchestrated within one software toolchain to result in a digital twin. 3. How to use the digital twin of a plant and a process for operator training, virtual commissioning and smart maintenance applications.

DETAILED EVENT INFO – SPECIAL SESSIONS

Special Sessions

These sessions are put on by other ISPE Boston Area Chapter committees throughout October and you are welcome to join any one of them!

Wednesday, October 7 12:00 pm – 1:00 pm	**CAREER DEVELOPMENT** ***Careers in Novel Therapies: A Discussion for Managers and Candidates*** **Panelists**: • Marika St. Amand, Chief Human Resources Officer, Intellia Therapeutics • Eliana Clark, Senior Vice President Technical Operations, Intellia Therapeutics • Mike Wourms, Vice President, Site Operations Head, Arranta Bio **Moderator**: Jesse McLaughlin, BioPharma Reginal Account Manager, Eastern US, Canada & Europe, Aqua-Chem **Session Leader**: Laura Berberian, CQV Engineer, DPS Group At the cutting edge of modern medicine, novel therapies are providing innovative ways to treat diseases and unmet medical needs. Developing and manufacturing these technologies requires companies to recruit, train, and retain top talent. This panel will discuss current talent acquisition and career development practices and trends from leaders at Intellia Therapeutics and Arranta Bio. Both managers looking to attract and promote top talent and candidates looking to break into these emerging fields are encouraged to join this discussion. This session will be a 45 minute panel with opportunity for audience interaction and polling, followed by a live Q&A.
Wednesday, October 14 12:00 pm – 1:00 pm	**CAREER DEVELOPMENT** ***Preparing Our Workforce for C&GT Manufacturing*** Presented by: Richard Tree, Vice President - North America, CAI Considerable industry focus on cell and gene therapy (both autologous and allogeneic) supply chain challenges exist today. The very short transport time from door-to-door (40–50 hours or less) under strict temperature specifications and chain of identity monitoring and control present its fair share of problems both predicted and yet undiscovered. But little attention appears to be given to the human element of the overall supply chain which includes the manufacturing process itself. Manufacturing equipment and their attendant automation systems have not kept pace with the evolving cell and gene therapy techniques. Consequently, the commercial processes tend to rely heavily on human operators manipulating benchtop equipment while handling live-cell samples with little to no room for error. Yet under these conditions, and in this environment, the chance of error or contamination increases dramatically. Then, consider that autologous therapies that rely on the biological material collected directly from the patient via apheresis, the stakes of any failure are higher than ever. The implications of operator error, in this case, are no longer the destruction of finished goods but rather can place the life of the patient in jeopardy. This talk poses the question, “what assumptions need to be challenged regarding the traditional model for talent development?” What can we learn from similar situations in our past? Looking back in history, a similar problem was identified by the U.S. during World War II when the country experienced a massive shortage of skilled workers who threatened

	the entire military supply chain. The implication of such a failure could be defeat in battle. Similarly, the implication of operator error in the supply chain could be defeat in a patient's battle with cancer. The solution during the war was a unique program called Training Within Industry (TWI). The same methodology could be the solution today while we wait on the fourth industrial revolution to unfold. This talk also introduces participants to the TWI methodology that is both relatively easy to implement and has proven to be highly successful – particularly since it was the precursor to the Toyota Production System. This session will be geared towards pharmaceutical and biotechnology manufacturers operating cGMP environments who might be struggling with the risks associated with accumulating low integrity data from their processes.
Wednesday, October 21 6:30 pm – 7:30 pm	**NETWORKING** ***Happy Hour Networking Mixer*** Hosted by the ISPE Boston Area Chapter Membership Committee Both members and non-members are welcome to join our Happy Hour Networking Mixer! This will be a great opportunity to connect with your colleagues in the industry during a facilitated networking hour meant to spark great conversations. Grab your favorite beverage and meet us on Zoom – we can't wait to see you!
Wednesday, October 28 4:00 pm – 5:30 pm	**WOMEN IN PHARMA®** ***Session on Implicit Bias*** Speaker info will be posted soon! All are welcome to join ISPE Boston's Women in Pharma® committee for an educational session on implicit bias. This session will be about 1 hour long and will include a Q+A session. Stay on with us and join in our professional moais – professional networking circles – so we can reconnect!
Friday, October 30 TIME TBD	**NETWORKING** ***Meet The Board: Town-Hall Style Q+A Session & Networking*** Hosted by the ISPE Boston Area Chapter Board of Directors All are welcome to attend this town-hall style Q+A session with the ISPE Boston Area Chapter Board of Directors. Meet the new leaders of the Chapter and hear what's next for the coming year. We're excited to meet and network with you!

SPEAKER BIOGRAPHIES (A-Z)

Chip Bennett, Assistant Director of Global C&Q, Commissioning Agents, Inc. (CAI)

A Project Manager and Senior Validation Engineer, Chip is a PMI® Certified Project Management Professional (PMP) with 20 years of experience in the pharmaceutical and regulated non-pharmaceutical industries and with expertise in risk-based verification, aseptic manufacturing, cleaning validation, quality systems, and owner project management. Chip is responsible for developing and implementing Quality Risk Management (QRM) based Commissioning and Qualification programs and projects, with a focus on assessing and training clients regarding development, implementation, and transition to risk-based approaches.

Michael Cody, Senior Solution Architect, NECI

Michael Cody - Mike is a Senior Solution Architect at New England Controls. He leads heavily integrated digital projects involving Manufacturing IT Infrastructure, Process Control Systems, Manufacturing Execution Systems, and Data Enablement. He was the overall integration technical lead for NECI on the Rubius Smithfield Project.

Nissan Cohen, President, Biopharmaceutical Water Doc

Nissan Cohen is President of Biopharmaceutical Water Doc. He is an industry veteran with over 40 years of experience in pharmaceutical water systems globally, in pharmaceutical/biotechnology, medical device, and mission-critical 24/7 process monitoring using Process Analytical Technology. He is an accomplished writer of over 35 technical articles published in Ultrapure Water, A2C2, Pharmaceutical Technology, Pharmaceutical Engineering, Semiconductor International, The Journal of the Institute of Environmental Sciences and Technology. Nissan is also Co-Chairman, Contributing author and Chapter Leader of International Society for Pharmaceutical Engineering's (ISPE) "Baseline Guide for Pharmaceutical Water and Steam Systems" Revisions 1, 2, and 3. Nissan's experience includes theoretical design, as well as practical deep knowledge of operational issues and pros/cons of various water systems, which he has seen in operations globally.

John Cunningham, Director & Industrial IT, RoviSys

John is the director of RoviSys™ business and industrial IT division, which focuses on IT infrastructure and cybersecurity for the process industries. In this role, John helps lead organizations in defining and developing effective cybersecurity strategies and I navigating IT-OT convergence. John has over 30 years of experience in the process controls industry.

Brian Feeney, Associate Director of Manufacturing Engineering, Rubius

Brian Feeney is the Associate Director of Manufacturing Engineering at Rubius' Smithfield, RI Manufacturing Site. Brian has over 15 years of experience designing, implementing, and operating process equipment and automation systems in the pharmaceutical manufacturing field.

Robert Hendrix, Process Engineer III, Thermo Fischer Viral Vector Services

Robert Hendrix is a Process Engineer focused on single use high throughput manufacturing designs with previous manufacturing, tech transfer, and facility / process design experience from AZ Biologics, CRB, and DPS Engineering. Current focus areas include streamlining tech transfer, optimization of single use supply chains, and high throughput manufacturing closed system designs and facility layouts geared toward gene therapy.

Rick Jarrell, Business Development Manager - Life Sciences, Eurotherm by Schneider Electric
Biography Coming Soon

Annelie King, PMP, Projects Manager, BWT Pharma & Biotech Inc.

Annelie King started out in Biotech in Sweden, but soon ended up in water treatment projects for Pharma & Biotech, which has been her passion for 20 years. Annelie was fortunate to become an expat and join different subsidiaries and joint ventures, focusing on Quality and Validation training and transfer. Today Annelie is Head of Project Management at BWT Pharma & Biotech Inc. at their office in Marlborough, MA. She is also a Simon Sinek fan.

Grace Linton, RA, AIA, LEED AP BD+C, Process Architect, CRB

Grace Linton has delivered projects in North America, Europe and Asia, covering a wide range of facility types, including monoclonal antibodies, vaccines, blood fractionation, active pharmaceutical ingredients, oral solid dosage, medical devices, fill finish, oligonucleotides and cell and gene therapies. As a lead process architect for designing Current Good Manufacturing Practice (CGMP) biopharmaceutical facilities, Linton is responsible for integrating the client's goals and programming criteria, regulatory requirements and building codes and standards into a cohesive facility concept.

Linton's design acumen is evident in design workshops where she draws from her broad knowledge in process, equipment and technology, CGMP operations and flows, and building systems to deftly construct a facility concept. Her dynamic design approach is supplemented by real-time 3-D modeling that serves as a communication tool for visualizing and exploring spatial concepts. Linton has a Bachelor of Arts in architecture from Washington University in St. Louis.

Paul Lopolito, Technical Services Senior Manager, STERIS Corporation

Paul Lopolito is a technical services manager for the Life Sciences Division of STERIS Corporation (Mentor, Ohio). He currently provides global technical support related to process research cleaners, stainless steel maintenance, and contamination control, which includes field support, site audits, training presentations and educational seminars. Paul has over 15 years of industry experience and has held positions as a technical services manager, manufacturing manager and laboratory manager. Paul is a frequent speaker at industry events and has published several articles and book-chapters related to cleaning validation and contamination control.

Martin Mayer, Business Development - Smart Engineering Services, ZETA GmbH

Martin Mayer is member of the Steering Commitee for the Plug & Produce activities within the ISPE Pharma 4.0 program. During his career a wide variety of senior roles from business development, research and development responsibility to general management, with more than 15 years experience. At ZETA he is responsible for business development in the field of Smart Engineering Services and Digitalization

Francesca McBride, Regulatory Specialist Director, Jacobs

Francesca McBride has more than 30 years of experience in the Pharmabio and Medical Device industries with an increased focus over the last 10 years in cell and gene therapy arena. She has provided Regulatory Compliance and Validation expertise to clients seeking facility and product licensing or accreditation by regulatory agencies, including the FDA, USDA, and the NIH/CDC in the US; and the EMEA, HPRA, ANVISA, MHLW, SFDA, CDSCO, WHO, PICS internationally. As an integral part of the Jacobs EPCMV teams, Ms. McBride has provided cGMP compliance direction to Jacobs clients and the project teams in the clarification and understanding in the application of international GMP requirements supporting facility design and the project planning/scheduling of the integration of construction, ASTM E2500 for commissioning and validation activities to support the project schedule and obtain regulatory approval.

Bill Olsen, Vice President of Construction Operations, Windover Construction

Bill has over 20 years of experience working with many of the region's leading life science, healthcare, and academic organizations including MIT Lincoln Laboratory, Brigham and Women's Hospital, Beth Israel Deaconess Medical Center, Boston Medical Center, Tufts University, Harvard Medical School, and the Broad Institute. Bill's technical expertise in preconstruction planning and project management successfully delivers construction of his clients' new facilities. He is recognized in the industry for building lasting client partnerships and for implementing forward-thinking solutions, such as construction technologies, on his projects.

Amr Raafat, Vice President of VDC and Technology, Windover Construction

Amr leverages the industry's most cutting-edge technologies to streamline the construction process. With 17 years of experience combining architectural, construction, and engineering expertise, Amr oversees Windover's VDC team and provides 4D animations, BIM coordination, laser scanning, drone mapping, virtual and mixed reality, digital fabrication, robotics, and 3D printing to enhance planning, change management, scheduling, site logistics, and safety throughout all construction phases. Working collaboratively with clients and project teams, Amr identifies the most effective technologies to support construction operations on each unique project. Amr earned his Master's degree in architecture from Boston Architectural College in Boston. In recognition of his pioneering work and vision to advance the construction industry, Amr received the prestigious 2019 Innovator of the Year award at the Autodesk Global AEC Excellence Awards.

Michael Rodionov, Principal Engineer, MMR Consulting

Michael is the principal of MMR consulting, a process engineering & validation consulting firm, specializing in clean utilities, and bioprocessing. Michael has been involved in Water system projects for over 10 years in Canada and the USA, experience including design, procurement, construction, commissioning, qualification, as well as operations & maintenance of pharmaceutical water systems. Michael combines his design experience with practical operational experience on water systems, to provide a valuable assessment of various technologies and options for the end-users.

Todd Rumsey, Process SME, Jacobs

Todd Rumsey is a senior process engineer with 20+ years of experience in the Pharmabio industry with a more recent focus on cell and gene therapy projects in the past 4 years. His recent experience includes leading the process design of a multi-process/product commercial gene therapy production and commercial autologous cell therapy facilities. He also has extensive experience involving the design of large scale bulk biologics facilities in addition to expertise with single-use facility concepts. Mr. Rumsey's skills include the optimization of process and utilities through computer simulation and the design of intelligent software tools. He has written articles and presented case studies on the economics of single-use systems.

Brita Salzman, Process Engineer, CRB

Brita provides clients with insight on how to better use resources to improve efficiency and works on a wide variety of projects, designing and optimizing biomanufacturing facilities. As she continues to build her resume with new and exciting projects, Brita has become passionate about delivering the next generation of medicine through Advanced Therapy Medicinal Products (ATMP), which encompass gene therapy, somatic cell gene therapy and tissue-engineered products. The current rise in cell and gene therapies has provided Brita the opportunity to showcase her ability to deliver value through creative design options. Brita graduated from the University of Colorado at Boulder with a Bachelor of Science in Chemical & Biological Engineering and a minor in Business. She keeps up-to-date on developments in biopharmaceutical engineering through the LA chapter of ISPE and has pursued a natural calling to be involved with Women in Pharma® through mentorship and networking.

Ankur K. Shah, PE, Sr. Process Engineer, DPS Group

Ankur Shah has over 13 years of process design experience, including in Novel Therapeutics such as cell and gene therapy, and RNAi. His expertise spans scoping studies through construction in Process Engineering and Project Engineering roles. Ankur has spearheaded engineering teams as Lead Process Engineer to accomplish project goals on time and within budget. His background encompasses biopharmaceutical, nuclear waste handling, mining, and petrochemical industries. Ankur holds an MS in chemical and biomolecular engineering from University of Pennsylvania, and a B.Tech in chemical engineering from the Indian Institute of Technology, Bombay.

Lynn Tokarczyk, Government Tax Incentives Consultant & President, Business Development Strategies, Inc.

Lynn Tokarczyk is the founder and president of Business Development Strategies, Inc. (BDS), the leading government tax incentives consulting firm in Massachusetts. Having honed her business skills as the founder and owner of an upscale women's retail boutique, she joined the Massachusetts Office of Business Development (MOBD) under the Cellucci administration as a project manager in 1995, later becoming a regional director. She was then recruited by Ernst & Young as manager for the New England Area State and Local Tax Incentives practice, rising to senior manager before starting her own firm, BDS, in 2003. BDS has built a team of subject matter specialists and provides a full range of services in real estate assessments, resident outreach, government incentives tax law, and more. Since its founding, BDS has helped negotiate and secure more than $100 million in tax incentives for privately and publicly held companies like Samsonite, Horizon Beverage, TripAdvisor, New England Ice Cream, MACOM, Analog Devices, Vicor, MilliporeSigma and Waters Corporation.

Richard Tree, Vice President - North America, CAI

As a Continental Vice President for CAI, Rich is responsible for the operations of North America for the company. He is a hands-on senior leader with extensive experience leading operational excellence efforts in diverse types of businesses. He is a creative thinker with an entrepreneurial mind-set, highly resilient, and exceptional at forming and building high-performance teams. His leadership has consistently strengthened each company's bottom line through improved organizational management and human performance. As a lean operations expert, he is personally credited with the lean transformation of 9 manufacturing sites, coaching over 34 manufacturing sites in advanced lean operations, and designing and implementing asset management strategies for multiple manufacturing sites.

Rich's professional career began during his career in the US Navy and has since held several key operations leadership roles in three manufacturing companies prior to joining CAI. He serves on the board of directors for the Metropolitan Energy Center, a non-profit organization in Kansas City.

He is currently studying for a Doctor of Engineering at George Washington University where his research focuses on decision making. He holds an MBA from Southern Methodist University and a Bachelor of Science degree from Columbia College.

Bill Whitford, Life Science Strategic Solutions Leader, DPS

William Whitford is the Strategic Solutions Leader at DPS Global with over 20 years of experience in biotechnology product and process development. His background is as an R&D Leader developing products supporting protein biological and vaccine production in mammalian and invertebrate cell lines. Products he has commercialized include defined hybridoma and perfusion cell culture media, fed-batch supplements and aqueous lipid dispersions. He has published over 250 articles, book chapters and patents in the bioproduction arena.