WEEK 1 / Track 1: Risk Management

Tuesday, October 6 11:00 am – 12:00 pm	***Session Info Coming Soon!***
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: Samuel Bessey, 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	***Session Info Coming Soon!***
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

ISPE Boston Area Chapter's Fall Education Summit

OCTOBER 2020

Schedule-At-A-Glance

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
27	28	29	30	1	2	3
				Welcome Email - Attendees receive their login instructions!		
WEEK 1 / TRACK 1: RISK MANAGEMENT						
4	5	6	7	8	9	10
		3:00 PM - EDUCATION SESSION *Developing a Cyber-Resilient Production Environment Using IT, OT & Security Team*		**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* **12:00 PM - EDUCATION SESSION** *How Pharma Can Identify Tax Incentives & Stop Leaving Money on the Table*		
WEEK 2 / TRACK 2: ATMP						
11	12	13	14	15	16	17
		3:00 PM - EDUCATION SESSION *Flexible Gene Therapy Facilities - Current Best Practices*		**9:00 AM - EDUCATION SESSION** *Viral Safety of Cleaned Surfaces Using a Risk-Based Approach* **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*		
WEEK 3 / TRACK 3: Facilities of the Future						
18	19	20	21	22	23	24
		11:00 AM - EDUCATION SESSION *Death to Welding (Analysis on High Throughput Closed Processing Strategies for Gene Therapy Manufacturing)*		**9:00 AM - EDUCATION SESSION** *Cold Water for Injection Generation & Distribution* **12:00 PM - EDUCATION SESSION** *Multi-Modal Facilities: Delivering Flexible, Future-Proof ATMP Facilities*		
WEEK 4 / TRACK 4: Pharma 4.0						
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* **3:00 PM - EDUCATION SESSION** *Risk Mitigation for Higher Levels of Data Integrity*		**9:00 AM - EDUCATION SESSION** *Keeping Pace with the Speed of Innovation: Facility Optimization through Construction Tech* **12:00 PM - EDUCATION SESSION** *How Digitalization Can Help Fast-Track Early Development to Manufacturing*		

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.

Samuel Bessey, Process Engineer, DPS Group

Sam Bessey offers a solid foundation in process engineering, having worked on projects in both the biotechnology and pharmaceutical fields. His projects have required close work with vendors and clients managing project budgets and timelines. Sam is highly skilled in developing PFDs and P&IDs, calculations, and equipment specifications for upstream, downstream, and utilities systems. His proven track record includes process safety and operability from experience participating in multiple risk assessments, HAZOPs, and reviews. Sam is highly adept at process design, problem solving, and the application of analytical skills in the biotechnology and pharmaceutical sectors, and holds a BS in Chemical Engineering from Lehigh University.

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.

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.

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

Biography Coming Soon

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

Biography Coming Soon

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.

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.