Pragmatic Approaches to Cleanroom Processing

Parenteral Drug Association Southeast Chapter Fall Conference Wednesday, November 6, 2019

8:00 – 8:30	**Registration/Breakfast**
8:30 – 8:45	Opening Remarks • Renee Morley, President SE Chapter
8:45 – 9:30	KEYNOTE: Thermofisher Scientific • Case Study on VR Technology and Training Aseptic Processors
	Panelist: Doug Rufino, Chris Binion, Angela Corbin (AR/VR booth- Earl Burris) Technology taking training to a new level. As pharmaceutical companies set high expectations for meeting customer product demands (as a CMO) and the patients/consumers needs for these products, metrics such as On-Time-Delivery (OTD) and Right-First-Time (RFT) must be continually evaluated to understand improvement opportunities to achieve the commitments. As RFT supports OTD, a RFT improvement initiative was established at the ThermoFisher Scientific Greenville NC site - Reduce Error, Fix It Attitude, Teamwork. The data assessment related to deviations drove some "quick win" implementation with additional longer term items. Among the longer term items was a look at training and specifically training related to new employees. Deviations were also higher among new employees. A team was identified to create training materials focused on fundamental principals required to provide strong foundational building blocks for aseptic operators, such as basic microbiology, engineering design, environmental design/testing along with regulatory expectations. The team identified the technologies of Augmented, Mixed Reality, and Virtual Reality for training platforms and also as job aids to assure consistent execution of activities across operators. ThermoFisher Scientific is implementing at the Cincinnati site use of Augmented Reality for packaging line clearance activities. The Training Center in Greenville is equipped with four 20' X 18' VR rooms which allows free moment of trainees within the production fill lines in the virtual reality realm. Multiple areas of VR training have been identified: line clearances, line set-up, operator movement within the aseptic area and aseptic techniques along with other areas/concepts. The use of VR technology brings a different level to the training platform for personnel by creating a self-paced, safe environment to practice techniques while mixed reality assists personnel with performance of tasks with direction and step execution within the production environment.  Doug Rufino is Sr. Director – QE, CPV, SA and XR technologies within ThermoFisher Scientific Global Engineering/Global Technical Operations. He has been in the pharmaceutical industry for 35 years. His experience cover various processes such as aseptic fill, Blow/Fill/Seal, and solid dose forms. He started in microbiological research with this as his primary background. He has held positions in R&D, Scale-up, QC, and QA which is where he has been most active. Doug was Corporate VP of Quality in Patheon from 2012 up to and including the acquisition by ThermoFisher. He current responsibilities include overseeing Quality Engineering, Continuous Process Verification, Sterility Assurance and Cross Functional Virtual/Augmented Reality platforms. Doug is a graduate of Rutgers University. He is married with four great kids (two college graduates and two attending college).

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	 Chris Binion is the Director of Augmented Execution Systems at Patheon, a part of Thermo Fisher Scientific, where he provides leadership in XR (augmented, mixed, and virtual) reality and its many uses within Pharmaceuticals. Chris has more than twenty years in the pharmaceutical, forensic, chemical, and biotech industries. He has led many new transformational initiatives throughout his career such as the International Train and Assist Mission (ITAM) in Iraq, RAMAN technology in forensic applications, and various analytical method and new technology development. More recently at Patheon, Chris has developed, championed, and led several transformational global programs to showcase innovation, excellence, and standardization. These include the Lean Labs Initiative, the Model Training Center, and global alignment and standardization of Data Integrity Governance. Currently, he leads the various cross reality programs for both training and utilization in manufacturing operations. His main objective is to enable employees to be successful and to systematically reduce risk to patients while increasing employee efficiency and effectiveness. Chris resides with his family in Alexandria, KY and volunteers at various non-profit organizations where he leads various leadership development and personal coaching. He serves as the District Commissioner for the Trailblazer District and Cubmaster for his son's pack.  Angela Algar-Swain Corbin is Sr. Manager Corporate Quality Assurance at ThermoFisher Scientific. Angela's current role is leading corporate improvement initiatives and assisting with roll out at site levels along with being an SME for site support related to sterility assurance and aseptic processing. She most recently led a group in development of "Back to Basics" training focused on fundamental principles required to provide strong foundational building blocks for aseptic operators. Angela has been in pharmaceuticals for 21 years supporting multiple areas in Quality roles: Aseptic Processing, Regulatory/Customer/Vendor Audits, Laboratories, Pharmaceutical Development, Visual Inspection, Continuous Manufacturing, Oral Solid Dosage, Facility Design/Installation/Qualification, and Training. Angela has a Bachelor of Science in Environment Health with double major in Public and Industrial Hygiene from East Carolina University. Angela lives in Washington, NC with her husband Jay and twelve year old son Deeson. Angela volunteers with her son's scout Troop as a merit badge counselor.  Earl Burris is a Technical Leader at Thermo Fisher Scientific, where Earl provides technical evaluation, implementation and training for new innovations including; augmented, mixed, and virtual reality. After spending more than twenty years in training and development, Earl has successfully implemented global support knowledge bases, online training programs, blended learning programs, and most recently the adoption of augmented and virtually reality. Earl has a diverse training and development background spanning; military tech ops, equipment manufacturing, remote monitoring, pharmaceutical CMO as well as technical service training. Earl is efficacious in leveraging, integrating and deploying new innovations and systems that have decreased total training time and costs while improving operational efficiencies and effectiveness. Earl resides with his family in Winston Salem, NC and is from Warsaw, OH and holds a AS in Business Technology along with certifications in SAT and ADDIE adult learning models.
9:30 – 10:00	• Vendor Show/Networking/Break
10:00 – 10:45	CASE STUDY: Pfizer – Finding Contamination in Filling Line
	Speaker: Darcy Adee and Kimberly Sicley Case study of gram negative bacteria contamination hidden within the filling line equipment.

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10:45 – 11:30	ADVANCES IN ROBOTIC ASEPTIC FILLING LINES: A COMPARATIVE STUDY Speaker: Hector T. Davila, LS&AM Global Technology Director, Fluor A large amount of the most important therapies for patients are classified as parenteral. The parenteral administration route requires aseptic filling of the drug product which is highly regulated due to the potential impacts to the individuals. Traditional filling lines require controlled environmental conditions, and equipment that are ever increasing capital and operational cost. Robotic aseptic filling lines are a potential disruptive force in the parenteral filling industry. This new filling line type has potential to significantly reduce cost of goods and increase patient accessibility to important new products. A comparative study was performed to evaluate robotic aseptic filling lines with traditional filling lines. The study focused on facility requirements in terms of HVAC classifications; floor space; floor-to-floor requirements; personnel, material, product and waste flows; relative facility operating costs, and rough order total installed costs.  Hector is a professional chemical engineer with over 35 years of experience in the pharmaceutical, chemical, and related industries. His expertise includes, providing technology leadership on pharmaceutical operations with concentration in Oral Solid Dosage (OSD), Fill and Finish (FF) and Active Pharmaceutical Ingredients (API) manufacturing.. He has served in a variety of roles for manufacturing and design firms, including process engineering, instrumentation and controls, process piping, project management, manufacturing operations, and design engineering.
11:30 – 12:00	Q & A Session for Thermofisher Scientific, Pfizer, Fluor
12:00-1:00	Lunch
1:00-1:45	CASE STUDY: Precision BioScience • Case study on working with CDMOs
	More than Audits: The Impact of Sponsor / CDMO Relationships on Quality Speaker: Bruce Stevens A case study on how relationships can influence the performance of Contract Manufacturing Organizations. Bruce is the head of the Quality and Compliance team at Precision BioSciences and specializes in developing and implementing phase-appropriate quality systems for emerging organizations. Prior to joining Precision, he was the Head of Quality at Liquidia Technologies, Furiex Pharmaceuticals, and Advanced Liquid Logic. Bruce also spent ten years in progressive roles at Biogen. He graduated with degrees in Biological Engineering and Biochemistry from Purdue University.
1:45-2:15	*Vendor break*
2:15-3:00	CRB – Gene Therapy Scale Up and Future of Manufacturing
	NextGen Now “The Future of Cell Therapy” Speaker: Emily Thompson ATMP processes have fallen back on manual operations to accommodate the patient specific scale, but what will these facilities look like in 5 years? The race for process closure and automated solutions has already begun. Don’t miss out as CRB discusses what will drive the industry to lower operating costs, more efficient staff utilization and improved reliability and product reproducibility. Emily Thompson is a Process Engineer at CRB, specializing in biological process and facility design. Over the last 16 years working in the biotechnology industry, she has gained expertise in designing facilities for monoclonal antibodies, vaccines, and gene therapy production, both in stainless steel and single-use. Emily is a specialist in process simulation and modeling and experienced in a number of different commercially available software programs. A graduate of North Carolina State University, Emily holds two degrees: a Bachelor of Science in Chemical Engineering and Bachelor of Science in Biochemistry. She is also a licensed Professional Engineer in the state of North Carolina.
3:00-3:45	FDA Invited
3:45-4:15	Q & A Session for Precision BioScience, CRB, FDA Invited
4:15 -4:30	CLOSING REMARKS & ADDITIONAL NETWORKING

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