PDA Southern California Chapter and PDA Capital Area Chapter together present

ALCOA+ in a World of DI

From coast to coast, it's everyone's responsibility...

This is a hot-topic refresher with real examples and real talk.

Wednesday, October 28, 2020 2:00 PM – 3:30 PM (EST)

PDA Southern California Chapter

Chapter President: Sheba Zaman, Head of Product Specialists and Training, Novatek

International

Scott Corbin, Director, Consulting, Azzur Group San Diego Dan Grill, Operations Manager & CSV Lead, Azzur Group San Diego

PDA Capital Area Chapter

Chapter President: Tita Tavares, Director, Consulting, Azzur Group Washington DC Judith McCorry, Director of Quality, Emergent Biosolutions Adil Seddiq, Technical Manager, Azzur Group Princeton

Abstract:

Providing the industry with a refresher and real-life examples of Data Integrity. Come ask questions in our 5-person panel discussion. The latest industry approaches with recent case studies. Improve your understanding of ALCOA+ and how you can apply it to your inspection readiness.

Sheba Zaman, Head of Product Specialists and Training Novatek International



Experienced Computer System Analyst with a demonstrated history of working in information technology within the Life Science industry. Strong information technology professional skilled in Data Integrity, Process Improvement, FDA compliance and Software Implementation/Optimization in a regulated environment.

Scott Corbin, Director, Consulting Azzur Group San Diego



Scott Corbin is the Regional Director for Azzur San Diego. With more than 25 years in the life science industry, Scott brings with him a robust and comprehensive skillset in manufacturing operations, quality assurance, auditing, and validation. Before joining Azzur, Scott worked across the industry, serving large enterprise businesses, as well as a number of start-ups. As the leader of Azzur San Diego, Scott builds robust teams focused on delivering effective and innovative solutions to client needs.

Dan Grill, Operations Manager & CSV Lead Azzur San Diego



Dan serves as the Operations Manager and CSV Lead for the San Diego regional office of Azzur Group. With a chemical engineering background, Dan has over 30 years' experience in Process Automation, Computer System Validation, Equipment and Utilities Validation, Project Management and Process Engineering. Industry experience includes: Pharmaceutical, Medical Devices, Food & Beverage, Chemicals, and US Military (contract). Dan has worked in Computer Systems Validation for over half of his career, validating such systems as PLCs, HMIs, DCSs, Enterprise Software, Server Farms, and Thin Clients. In his current role as Operations Manager, Dan oversees a team of engineers dedicated to making our customers successful on capital projects in the pharmaceutical, biotech, and medical devices industries. Dan is a member of ISPE.

Tita Tavares, Director, Consulting Azzur Group Washington DC



Tita brings with her more than a decade of comprehensive operations experience in the biotech and biopharmaceutical industries, including consulting, business development, marketing, business intelligence, and management. As the leader of Azzur Washington, DC, Tita is responsible for growing Azzur's footprint to meet the increasing demand for excellence in life science consulting in Washington, DC, Maryland, and Virginia.

In addition to her professional experience, Tita is a dedicated advocate of industry and educational associations. Among her various appointments, Tita is President of the PDA Capital Area Chapter. Tita graduated from Platt College with a bachelor's degree in visual communications.

Judith Adair McCorry, Director of Quality Assurance Emergent BioSolutions



My career in pharmaceuticals began in 2002 as a quality control associate who specialized in quality control and environmental monitoring in the aseptic manufacturing of intravenous drug products.

After several years of experience in the microbiology side of quality control, I was given the opportunity to leverage my chemistry background to lead the start of a chemistry laboratory to support testing of phase 1 and 2 clinical products for a small biotech start-up. Because of my quality control experience in both microbiology and chemistry, I was given the responsibility of leading stability testing to support new drug applications.

After gaining experience in managing the stability testing program, I moved to the technical operations part of manufacturing, supporting several product franchises and business units in

continuous process enhancements/improvements, validation, and investigations. Because of my strong technical background and writing ability, I lead a site-wide project tasked with creating new procedures for performing and writing investigations; including a corrective and preventative actions program.

Throughout my career, I've had extensive collaborative interactions with the FDA's Center for Biologics Evaluation and Research as well as foreign regulatory agencies such as the European Medicines Agency (EMEA), Medicines and Healthcare products Regulatory Agency (MHRA), and the National Medical Products Administration (formerly China FDA).

Aside from the strategic and tactical side of quality control, I also have a passion for mentoring and helping my peers and colleagues in their own career development. The Master of Leadership Development I will soon have, focuses on how to be an authentic and transformational leader, leading high-performing teams. The concurrent MBA degree that I am pursuing is also helping to develop my business acumen as I rise to higher levels of leadership.

Adil Seddiq, Technical Manager Azzur Group Princeton



Adil Seddiq is a Technical Manager with Azzur Group. With more than 17 years of FDA-regulated industry diverse experience in small molecule/biopharmaceuticals, secondary packaging and equipment manufacturing. Throughout his career, Adil has specialized in Computer Systems Validation, Risk Management, Inspection/Audit Management, and Vendor Management through Validation and QA positions at Eli Lilly & Co. and Glatt Air Techniques. He is a recognized subject matter expert on risk-based systems validation, process improvement, and quality culture.