PDA Southeast Chapter November Series

November 10 – Tuesday-Two Sessions

2:00 pm – 4:30 pm

Risk Management in Quality Systems

https://www.eventbrite.com/e/pda-southeast-chapter-risk-management-in-quality-systems-registration-126968988663

2:00 pm – 3:15 pm

Keep Bugs at Bay – a risk-based pest control assessment

211 CFR requires a building free of infestation by rodents, birds, insects, and other vermin – but HOW to control these types of pests in your facility can be tricky. A risk-based approach can help us efficiently assess our facilities in terms of criticality and provide a roadmap for a successful pest control program. Join us to learn how to apply QRM to your new or existing pest control program!

Tiffany Baker

Tiffany Baker is a quality risk management and microbiology consultant with Concordia ValSource, LLC. She specializes in development and implementation of innovative approaches to quality risk management (QRM), QRM program design, creating a risk-focused culture, and developing risk-based approaches to support contamination control strategies. Tiff is an active member of the Parenteral Drug Association (PDA), a faculty member for PDA's Training Research Institute, and an instructor for the PDA courses on quality risk management foundations, practical application of QRM tools, and QRM for the design, qualification, and operation of manufacturing systems. Additionally, she was a member of the core team who co-authored the ISPE Baseline guide 5 - Commissioning and Qualification, incorporating QRM into the process. She has a BS in microbiology from the University of Rhode Island and is currently pursuing an MBA from Providence College.

3:15 pm – 4:30 pm

Risk Based Cleaning Validation Life Cycle

An effective cleaning validation program is essential for a successful regulatory inspection. Over the years, it has been a challenge for industry to develop an effective cleaning validation program that meets regulatory expectations. A robust cleaning validation program includes strategies for procedure development, product families, product contact equipment, training, analytical methods, analytical sampling, acceptance criteria and cleaning validation

methodology. This presentation session provides a roadmap to apply FDA's Process Validation Life Cycle approach and ICH Q9 Quality Risk Management core principles to cleaning validation programs. This session will help to learn how to develop a safer, compliant and efficient cleaning validation program.

Sunil Patel

Sunil has a M.Sc. Chemical Product Design: Loughborough University, United Kingdom and a
B.E Chemical Engineering from South Gujarat University, India
He has over 15 years of experience working in the engineering and validation fields of cGMP / FDA / EU / ISO regulated industry sectors.

Sunil has a strong background in Cleaning Validation (CIP, COP, Manual), Process Validation, Process Design, Clean Utilities (WFI, PW, Clean Steam, Clean Air, Clean Gases), HVAC, Project Management, Sterilization and Processing Equipment Validation. Further expertise includes Process Optimization/Improvement, Regulatory Compliance and Risk Management methodologies for the pharmaceutical and biologics industry.

Prior to joining Ecolab, Sunil has had variety of Validation roles as consultant and corporate employee with increased responsibilities within Pharmaceutical and Biologics industry including Catalent, Eisai, Pfizer, Teva and Novartis.

Sunil started his career in 2005 as a Project Engineer consultant in the United Kingdom, overseeing start-up, commissioning and validation activities for various pharma clients. He has expertise for developing cost effective, safer, and compliant Cleaning Validation programs. Over the years, Sunil has successfully led numerous complex cleaning projects utilizing risk management tools to identify and mitigate cross-contamination risks. He has developed and implemented standardized cleaning validation practices globally with effective training program. Further experience includes change management, manufacturing non-conformances due to cleaning failures, and auditing cleaning validation programs.

Sunil joined Ecolab in April'2018 and is currently a Senior Global Technical Manager for Ecolab Life Sciences. In this role as an industry expert Sunil provides support and guidance around CIP/COP/Manual cleaning validation practices in a GMP manufacturing operations to our global sales team and customers. In addition, the role also involves providing customer support for writing, execution and project management of cleaning validation studies, developing cost effective, safer and compliant cleaning validation program, cleaning process optimization, and conducting site surveys for cleaning validation program.

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November 11 - Wednesday
2:00 pm – 4:30 pm

Microbiological Series

https://www.eventbrite.com/e/pda-southeast-chapter-microbiological-series-registration-126975642565

2:00 pm – 3:15 pm

How to keep up with seasonal changes and microbial trends in the lab

Trending is an important aspect of microbial control in pharmaceutical manufacturing environments. Seasonal changes can impact operations and contamination risks so looking at microbial history is a valuable tactic, especially when considering fungal isolates.

Charles River's microbial identification laboratories process over 450,000 samples annually, and our case study will share the top 5 fungal species we see and explain why these organisms thrive in the autumn months.

This example will help understand which species you may encounter and show how trending can aid informed decision-making.

Join this session to learn how autumn seasonal changes may affect your cleaning programs.

Duncan Barlow

Duncan Barlow is the Technology and Market Development Manager for Charles River's Microbial Solutions division, specializing in Accugenix® microbial identification and strain typing.

He holds a BSc. from the University of Stirling and has over 20 years of experience spanning microbial testing, new technology adoption and implementation in the pharma, food and clinical industries.

His current role with Charles River supports customers in implementation of microbial identification solutions across the globe. He has substantial

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experience with other QC micro contamination control offerings such as endotoxin testing, rapid microbiological methods and environmental monitoring.

3:15 pm – 4:30 pm

Continuous Microbiological Environmental Monitoring for Aseptic Manufacturing

Biofluorescent particle counters (BFPC) offer an alternative method for viable air testing that provides continuous, real-time results with improved detection. Not only does this provide better understanding of the aseptic manufacturing process and remove the contamination risk from interventions, it also eliminates the data integrity issues associated with the highly manual culture-based methods that are used today. This presentation will review the technology used by these instruments and how to use them to improve your process understanding and reduce risk, all while assuring a higher level of data integrity.

Mike Dingle

Mike Dingle is a Field Application Specialist at TSI where he provides application support for the BioTrak Real-Time Viable Particle Counter and other TSI products used to test and monitor controlled environments. Prior to joining TSI, Mike worked as a QC Microbiologist in the pharmaceutical and medical device industries for over 20 years where he developed and managed environmental monitoring programs for a wide variety of controlled environments.

Carol Julich

Carol Julich is the senior sales specialist at TSI working in the contamination control division and has been with TSI for 6 years. Carol is responsible for the sales of the particle counter line, active air samplers and the BioTrak. Carol has over 20 years' experience in contamination control. Prior to TSI Carol worked for Millipore Sigma and BioTest Diagnostics.

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This sponsorship allows you have a 3 minute recorded message during the session on November 10th. Great for company intro. Logo will be on all eblasts before and after the event. $300

This sponsorship allows you have a 5 minute recorded message during both sessions on November 10th & 11th. Great for company intro. Logo will be on all eblasts before and after the event. $500