



Microrite, Inc. brings you this unique learning experience in Importance of Qualified Microbiologists for an Audit Team; Part of Microrite's step-by-step webinar series.

Importance of Qualified Microbiologists for an Audit Team

Contract manufacturer or contract laboratory audits are often performed by the sponsor quality team or a contract GMP auditor. Majority of issues related to contaminated product are related microbial contamination. It is crucial to understand facilities, utilities, process, cleaning and testing related gaps at the contract facility to avoid excessive investigations or un-releasable batches. This scenario is not uncommon, hence having a qualified microbiologist with overall understanding of contamination risk in manufacturing and testing is extremely important during audits.

When?

October 10th, 2017

1:30pm to 3:30pm

Eastern Daylight Time

Which industries does this webinar apply to?

Pharmaceuticals, Biotechnology, In-Vitro Diagnostics and Medical Device

Who will benefit?

Quality Assurance, Microbiology, Regulatory Affairs, R&D, Manufacturing and Training Personnel



Importance of Qualified Microbiologists for an Audit Team

October 10th, 2017

Benefits to the participants:

- Facility design and barrier system integration is a crucial part of aseptic manufacturing; so is maintenance and monitoring
- Monitoring data may look adequate and may not capture contamination risks if sample selection is not risk based
- Utilities design, maintenance and testing may not be noticed till contamination or endotoxin issues are noticed in product
- Excessive cleaning or inadequate cleaning and disinfection; both may lead to contamination issues
- Understanding process related issues leading to failed product
- Laboratory design and testing deficiencies that lead to false negative or false positive results

Who will be teaching?

Ziva Abraham is the President and Founder of Microrite, Inc., a California based consulting firm providing consulting and training services to pharmaceuticals, biotechnology, medical devices and in vitro diagnostics in the areas of quality assurance, quality control, microbiology, and validation. Ziva has over 25 years of academic, research, clinical and industrial experience in microbiology, and quality assurance. Ziva has received her Master's Degree in microbiology and has conducted research on developing microbial Insecticides using entomogenous bacteria and fungi. Her career also includes founding and managing clinical laboratories for Maccabi Medical in Israel. She has trained personnel from various industries in microbiology techniques and methods. She uses her extensive experience to teach why assessing risk of microbial contamination should be in the forefront of any company that has products for human/veterinary use. Her experience in clinical laboratories has provided her with the framework to understand the effects of microbial contamination in products from a patient safety perspective.

Microrite focuses on helping companies with contamination control, microbiological quality control for sterile and non-sterile manufacturing, quality assurance, and validation.

