



Microrite, Inc. brings you this unique learning experience in Performing and Documenting Risk Analysis for Microbiological Testing Failures; Part of Microrite's step-by-step webinar series.

Performing and Documenting Risk Analysis for Microbiological Testing Failures

Assessing microbial contamination risk is one of the most difficult parts of a microbial testing failure investigation. Regulators expect companies to assess risks, and it is the right thing to do to avoid harm to the patient. However making the decision whether there is risk to the patient or not requires a broad breadth of expertise including clinical microbiology expertise, an understanding of the level of contamination to the level of risk, and also knowing with certainty if risk is present or not.

Microbes adapt; as we all very well know from the many recalls and warning letters that organisms that were previously not known as infectious agents have caused harm to patients, and the list of objectionable organisms keeps on increasing due to the population of immunocompromised patients and nosocomial infections.

When?

November 20th, 2015
1:30pm to 3:30pm
Eastern Standard Time

Which industries does this webinar apply to?

Pharmaceuticals, Biotechnology, Medical Device, Cosmetics, In Vitro Diagnostics, and Hospitals

Who will benefit?

Quality Assurance, Quality Control, Microbiology, Facilities, Manufacturing, Materials, Regulatory Affairs, R&D, Pharmacy, and Training Personnel



step-by-step webinar series

Performing and Documenting Risk Analysis for Microbiological Testing Failures

November 20th, 2015

Benefits to the participants:

- Where is the failure
 - Environmental monitoring
 - Process related bioburden
 - Microbiology testing
- What is the level of contamination (CFUs) - this is critical in determining risk
- What is the organism
 - Is the identification validated?
 - Is the source known?
 - Was this organism seen before?
- Is it the organism and/or the byproduct that will harm the patient?
- Can the organism and/or the byproduct be removed?
- Level and frequency of infections reported due to the contaminant
- Where, and how to research clinical implications of the organism(s) in question

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.



REGISTRATION FORM

Performing and Documenting Risk Analysis for Microbiological Testing Failures

Personal Information of One Registrant	
Last Name: Mr. Ms. Dr.	First Name:
Job Title:	Organization:
Mailing Address:	
Telephone:	
Email:	
Fee: (see fee structure below, all costs are per person)	
<input type="radio"/> 1 attendee \$225 <input type="radio"/> 2-5 attendees \$180 (per person)(20% Discount) <input type="radio"/> 6-10 attendees \$153 (per person)(32% Discount) <input type="radio"/> 11 or more attendees \$135 (per person)(40% Discount)	
<p>Method of Payment: Credit Card and Check payments only. Attendees can register and make payments on Microrite’s website: www.microrite.com or complete this form and fax to 408-445-1236. Check payments must be cleared before the webinar date. If you have any questions regarding payment methods feel free to contact Microrite at 408-445-0507 or send your enquiry to webinars@microrite.com.</p>	
<p>Confirmation of registration will be sent via email. For credit card payment on website, a payment receipt will be considered as confirmation of registration. For credit card information faxed to Microrite an email confirmation will be sent with a copy of payment receipt. Please call 408-445-0507 in due time if confirmation is not received after payment. Webinar cancellation must be received 3 business days prior to the webinar less a 10% service fee, cancellation requests will be accepted via email only. All refund requests must be made by the organizations primary contact or credit card holder. Refunds will be credited to the original credit card used to purchase the webinar.</p>	

