Microrite, Inc. brings you this unique learning experience in Objectionable Organisms-A Challenge and Dilemma; Part of Microrite's step-by-step webinar series.

#### **Objectionable Organisms-A Challenge and Dilemma**

The topic of objectionable organisms is often discussed, but defining what is objectionable is a challenge, mainly as the QC microbiologist rarely knows the patient population, the immune health of the patient and may not have clinical microbiology background making it difficult to know where to start.

In the FDA's words, "For a variety of reasons, we have seen a number of problems associated with the microbiological contamination of topical drug products, nasal solutions and inhalation products. The USP Microbiological Attributes Chapter <1111> provides little specific guidance other than "The significance of microorganisms in non-sterile pharmaceutical products should be evaluated in terms of the use of the product, the nature of the product, and the potential hazard to the user."

It is difficult to determine what organism would be objectionable in a specific product unless the quantity, infectivity, pathogenicity as well as the virulence of the said organism is known.

#### When?

October 24<sup>th</sup>, 2018 1:30pm to 3:30pm Eastern Standard Time

#### Which industries does this webinar apply to?

Pharmaceuticals, Biotechnology, Medical Device, and In Vitro Diagnostics

#### Who will benefit?

Quality Assurance, Quality Control, Microbiologists, Facilities, Regulatory Affairs Manufacturing and Training Personnel



### **Objectionable Organisms-A Challenge and Dilemma**

## October 24<sup>th</sup>, 2018

#### Benefits to the participants:

- Regulator's expectations regarding objectionable microorganisms
- Confirm the identification, invalid identification may lead to erroneous research
- Understand the methods in which bacteria and fungi cause harm to the patient-each have a different mode
- Confirm that the organism is a true pathogen or an opportunistic pathogen
- Understand at what levels does it become pathogenesis-virulence factors need to be understood before coining the organism objectionable
- Verify the extent of pathogenicity through geographical occurrences
- Evaluate morbidity and mortality data related to the pathogen
- Assess emergence of re-emergence of the organism as a pathogen
- Learn how to conduct research and assess risk to patient.

#### 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 worked on developing microbial insecticides using entomogenous bacteria and fungi towards her doctoral research. 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.



#### **REGISTRATION FORM**

## **Objectionable Organisms-A Challenge and Dilemma**

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 attendee)						
○ 1 attendee \$	225					
2-5 attendees \$180 (per attendee)(20% Discount)						
○ 6-10 attendees \$153 (per attendee)(32% Discount)						
11 or more attendees \$135 (per attendee)(40% Discount)						
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.						

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.



# **Objectionable Organisms-A Challenge and Dilemma**

Additional Attendees					
	First and Last Name	Email			
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					



# **Objectionable Organisms-A Challenge and Dilemma**

Choose One (Place X) ▶	VISA	Master Card	American Express		
Card Holder's Name ▶					
Address of Card Holder:	Enter firm address for corporate card or personal address for personal card				
Street:					
City/State:					
Zip Code:					
Country:					
Contact Ph No & Email:					
Card Number:					
Expiration(Month/Year):					
Amount (US Dollars):					
Signature:					
Name of Attendee(s)					
Referred by:	Kindly note the name of the company or person that referred you to this workshop. We would like to thank them.				

# MICRORITE WHEN EXPERTISE MATTERS