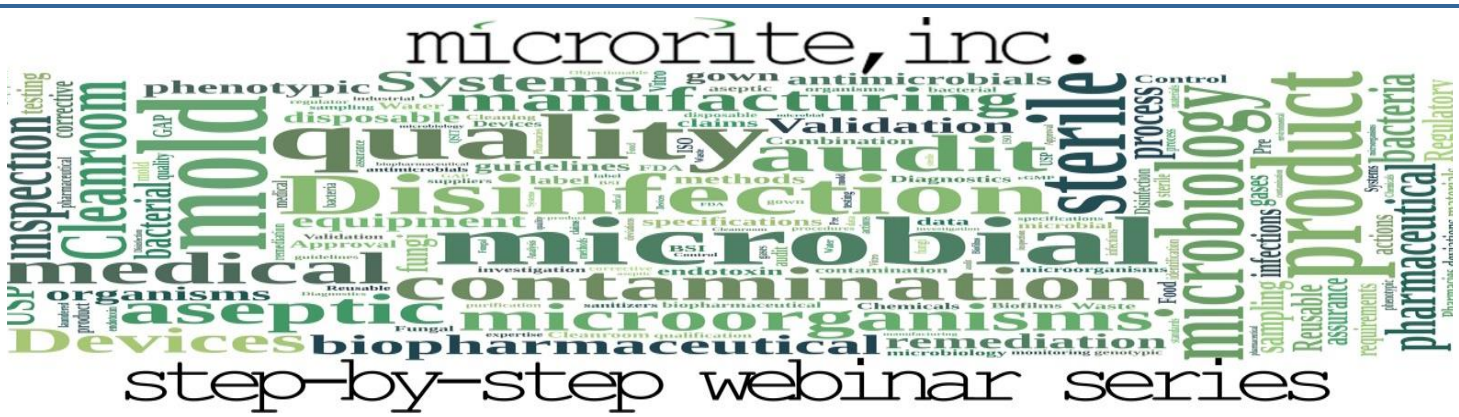

Microrite, Inc. brings you this unique learning experience in Contamination Due to Human Borne Organisms-Causes and Solutions; Part of Microrite's step-by-step webinar series.

Contamination Due to Human Borne Organisms-Causes and Solutions

Majority of the sterility and media fill failures are due to human borne contaminants. There are a few reasons for this to occur. To time consuming investigations and excessive CAPAs without a resolution it is important to perform risk assessment for facility design and integration including airflow patterns to avowing airflow over the operator over open product during the design and verification of a new facility build. Since personnel are a repository of microbes, avoiding microbes from personnel into the critical environment as well as open product should be assessed during gown and glove choice and development of the gown and glove maintenance program. Comfort of operators and ergonomics also plays a key role in such contamination issues.

Learn from case studies how human borne contamination issues can be reduced by evaluating the systems that are the key sources.

When?

June 28th, 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

Microrite, Inc. 5019 New Trier Avenue + San Jose, CA 95136 + Ph: 408-445-0507 + Fax: 408-445-1236
www.microrite.com

Contamination Due to Human Borne Organisms-Causes and Solutions

June 28th, 2018

Benefits to the participants:

- How excessive contamination events have led to data integrity issues, warning letters and export bans
  - Case studies related to flawed barrier system design and integration
  - Case studies related to gaps in gown choice an maintenance
  - Case studies where operator discomfort and ergonomics led to failures
- Understand cleanroom an barrier system flaws that will lead to human borne contamination of product
- Learn what needs to be evaluated when choosing and maintaining gowns
- Reasons why ergonomics and operatory comfort is important and how ignoring these can lead to human borne contamination
  - Operators and analysts are not the only ones to be held responsible for good aseptic techniques. Training and retraining of operators will not resolve human borne contamination issues, if the proper tools are not provided along with effective training, these issues will persist.
- Laboratory design flaws that lead to sterility test failures or failing bioburden results with human borne contaminants

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 Ph. D degree. 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, Inc. 5019 New Trier Avenue + San Jose, CA 95136 + Ph: 408-445-0507 + Fax: 408-445-1236
www.microrite.com

REGISTRATION FORM

Contamination Due to Human Borne Organisms-Causes and Solutions

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.	

Microrite, Inc. 5019 New Trier Avenue + San Jose, CA 95136 + Ph: 408-445-0507 + Fax: 408-445-1236
w w w . m i c r o r i t e . c o m

microrite, inc.

step-by-step webinar series

Contamination Due to Human Borne Organisms-Causes and Solutions

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		

Microrite, Inc. 5019 New Trier Avenue + San Jose, CA 95136 + Ph: 408-445-0507 + Fax: 408-445-1236
www.microrite.com

microrite, inc.

step-by-step webinar series

Contamination Due to Human Borne Organisms-Causes and Solutions

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

Microrite, Inc. 5019 New Trier Avenue + San Jose, CA 95136 + Ph: 408-445-0507 + Fax: 408-445-1236

www.microrite.com