Mold Contaminations-Prevention, Investigation, Remediation and Risk Assessment
Durham, NC
September 17th & 18th, 2018

In recent years Mold Contaminations and Recalls have been a focus of attention for the FDA. The wave of mold related inspections and recalls are in response to a deadly fungal meningitis outbreak linked to contaminated steroids from a now infamous compounding pharmacy and a wave of high profile recalls. A risk-based approach to mold is required in order to prevent a catastrophic outcome

There is no one solution for preventing, controlling and remediating mold contaminations. The same mold may be detrimental in one product but may have no clinical implication in another. Understanding mold, its proliferation methods and its clinical relevance is the solution. The key is not to panic at the first sight of mold.

Environmental monitoring programs which are not risk based rarely track mold thus prevention cannot be practiced. Disinfection is misunderstood in relation to mold proliferation, hence disinfection programs may not kill mold and conducting efficacy studies does not provide holistic solutions. Many times facility design, maintenance and airflow patterns are not adequate and mold may spread within the cleanroom or barrier system due to these deficiencies. A product passing <USP> antimicrobial efficacy test does not guarantee that no mold will grow in the product as preservatives/antimicrobials are tested against easy to control mold.

While non-sterile production facilities do not require stringent environmental controls, many mold species are still detrimental in certain non-sterile products.

Mold proliferation, prevention and control are not understood because there is a gap in mycological expertise within the pharmaceutical industry. Microrite invites you to attend this never before offered intensive workshop.

A mycologist who has been conducting mold contamination investigations for over 25 years teaches this course.

Which industries does this workshop apply to?

Pharmaceuticals, Biotechnology, Medical Device, and In Vitro Diagnostics, Nutraceuticals and Pharmacies

Who will benefit?

QC Microbiologists, Manufacturing, Quality Assurance, Validation, Facilities and Training

Microrite, Inc. 5019 New Trier Avenue + San Jose, CA 95136 + Ph: 408-445-0507 + Fax: 408-445-1236
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Day 1

Understanding Mold (Hands-On Exercise)

Understand mold classes, sporulation patterns and how easy to kill mold can switch its proliferation method where the spores are impossible to eradicate.

- This will be a hands on exercise using fungal reference texts and images
- This exercise will allow attendees to understand that no matter what method you use, you may not always have the correct identification.
- Learn about the sources of various cleanroom mold isolates and develop a prevention plan
- Understand where and how these mold can proliferate in your facility
- Case studies where extensive investigations and CAPAs have led to little or no remediation
- Discussion on FDA 483s related to mold contaminations

Mold Myths and Facts (Classroom Discussion)

- Myths about disinfection and disinfectant qualification related to mold removal
- Understanding the fungicidal activity of various disinfectants used in the industry
- How fungicidal label claims are established and why they could be misleading
- Dispelling myths about resistance of mold to disinfectants-some mold is hard to kill
- Common errors in disinfectant efficacy testing that gives false confidence in mold kill
- Cleaning practices that actually encourage mold growth
- Contact time myth – understand that disinfectant activity does not stop at 10 minutes
- Antimicrobial/Preservative efficacy testing deficiencies-Understand the type of mold tested for efficacy vs other mold types found in cleanrooms

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Day 2

Investigating Mold Contaminations (Classroom Discussion)

Often the risk of mold contamination is not addressed until contamination has happened!
Understand how mold gets into your facility and how it can grow in the facility and in process materials. This can assist a company to comprehend possible mold contamination of the product.
Occasionally mold contamination leads to major facility and process design changes after it has made its presence known in the cleanroom in large quantities or has ended up in the product.

- Understand why investigating and managing mold contamination can be difficult without proper knowledge of mold and controlled environments
- Points to consider when investigating mold contamination
  - Facilities
  - Materials
  - Raw materials
  - Process
  - Product
  - Laboratory environment and equipment-a common cause of mold related failures
  - Growth media quality and storage-a common cause of false positive mold results
  - Cleaning supplies and cleaning procedures
- Why excessive cleaning and disinfection or fogging is not the solution when it comes to cleanroom contamination by mold

Clinical Relevance of Objectionable Mold (Classroom Discussion)

Learn about what mold is objectionable via which mode of administration

- Mold Infections of the central nervous system
- Systemic mold infections
- Mold infections via nasal and inhalation pathway
- Cutaneous and sub-cutaneous mold infections
- Vaginal and rectal mold infections
- Oral mold infections
- Nosocomial mold infections
- Growth of mold infections over years
- Guidelines on how to assess risk of mold in your product
- Understanding the level of risk and making changes to remediate the situation

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AGENDA

September 17th & 18th 2018	North Carolina Biotechnology Center Hamner Conference Center- Congressional Room 15 TW Alexander Dr, Durham, NC 27710
Day 1 Agenda	
Registration and Breakfast	8.00 AM to 8.30 AM
Understanding Mold- Hands on Exercise	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Understanding Mold- Hands on Exercise (cont.)	10.30 AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Mold Myths and Facts- Classroom Discussion	1.00 PM to 3.00 PM
Break	3.00 PM to 3.15 PM
Mold Myths and Facts- Classroom Discussion (cont.)	3.15 PM to 4.15 PM
Questions and Answers	4.15 PM to 5.00 PM
Day 2 Agenda	
Breakfast	8.00 AM to 8.30 AM
Investigating Mold Contamination- Classroom Discussion	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Investigating Mold Contamination- Classroom Discussion (cont.)	10.30 AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Clinical Relevance of Objectionable Mold- Classroom Discussion	1.00 PM to 3.00 PM
Break	3.00 PM to 3.15 PM
Clinical Relevance of Objectionable Mold- Classroom Discussion (cont.)	3.15 PM to 4.15 PM
Questions and Answers and discussions	4.15 PM to 5.00 PM

Hotel Recommendations:
*Microrite does not have a room block at any hotel. Please choose what you feel comfortable with.

Airport:
Raleigh-Durham International Airport (RDU)

Parking:
The Hamner Conference Center provides free parking a short (less than ½ block) walk from the building.

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REGISTRATION INFORMATION

Personal Information of One Registrant		
Last Name: Mr. Ms. Dr.		First Name:
Job Title:		Organization:
Mailing Address:		
Telephone:		
Email:		
Fee: $1800.00 per attendee (Includes 2 day workshop fee, breakfast, lunch, break, and course material)		
Additional Attendees		
First Name:	**Last Name:**	**Title:**
First Name:	**Last Name:**	**Title:**
First Name:	**Last Name:**	**Title:**
First Name:	**Last Name:**	**Title:**

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 workshop date. If you have any questions regarding payment methods feel free to contact Microrite at 408-445-0507 or send your enquiry to labraham@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.

Workshop cancellation must be received 15 business days prior to the workshop less a 10% service fee, cancellation requests will be accepted via email only. The organizations primary contact or credit card holder must make all refund requests. Refunds will be credited to the original credit card used to purchase the workshop.

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PAYMENT INFORMATION

Choose One (Place X) ►	**___ VISA**	**___ Master Card**	**___ American Express**
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Address of Card Holder:	Enter firm address for corporate card or personal address for personal card		
Street:			
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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.		

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About the Presenter

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 with a focus on Mycology and has conducted research on developing microbial Insecticides using entomogenous bacteria and fungi for her PhD 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.

Company
Microrite's goal is to provide practical solutions through consulting and training

Consulting Services
Microrite is a San Jose, CA based Consulting Company helping Pharmaceuticals, Biotechnology, Medical Devices, In-Vitro Diagnostics and Combination products in the areas of Quality Assurance, Microbiology, Process Development, Process Validation, Facility and Utility Validation

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