microrite

Investigations Bootcamp

Particulate and Microbial Investigations Workshop

June 8th-9th, 2020

Cambridge, MA

Microbial and particulate contamination has many consequences; patient harm, failed media fills, inconclusive investigations and continuing contamination events are frequently associated with voluntary or involuntary plant shutdowns, product recalls, and warning letters.

This comprehensive two day course on investigation of microbial and particulate contamination in cleanrooms, manufacturing processes, laboratory testing, and product will provide the tools for conducting in-depth fact based and scientifically sound investigations. Investigations are costly and labor intensive; detection of microbial and particulate contamination requires prompt attention and a good understanding of contaminants.

Which industries does this seminar apply to?

Pharmaceuticals, Biotechnology, Medical Device, In Vitro Diagnostics and Cleanroom Equipment Suppliers

Who will benefit?

Quality Assurance, Quality Control, Microbiologists, Validation, Facilities, Manufacturing and Engineering


June 8th and 9th, 2020- 8:00am to 5:00pm


Courtyard by Marriott-777 Memorial Drive, Cambridge, MA, 02139


$1,850 per attendee (group discount available: 2-4 attendees 10%, 5+ 20%)


Register at www.microrite.com


Email questions to info@microrite.com

Particulate contamination in cleanrooms and barrier systems
Airborne particle contamination associated with cleanrooms, RABS and Isolators may be an indication of design issues, mechanical wear, operator deviation from SOPs or evidence of compromised or aging facilities. In order to conduct an investigation related to airborne particle contamination, a comprehensive understanding of air flows related to the sample location as well as activities being performed at that particular time is needed. Review of cleanroom and barrier system qualification can be useful in investigation of particle related contamination.

- Importance of cleanroom classification in conjunction with the process
- The use of risk analysis tools such as smoke studies for evaluating air flow patterns when performing particle and microbial investigations
- Understanding of particle sample volumes for monitoring and classification testing
- Assess the source of contamination by utilizing particle size and other parameters

Particulate contamination in products
Particulate contamination can come from several different sources; the solution itself, any added ingredients, the production process, environmental factors, product packaging and more.

- Identifying particle characteristics is the first step to investigating particulate contamination in product
- Understand the clear and hidden sources of particulate contamination
- Learn about particulate contamination issues from case studies and FDA 483 observations
- Common mistakes made when investigating particulate contamination in product

Why validate microbial identification results
Conducting a full-on investigation without confirming the validity of microbial identification is a futile exercise, costing time and resources. This session will focus on the numerous ways a false identification can be obtained by:

- Explaining the differences between phenotypic and genotypic identification
- Understanding the limitations of conventional and automated methods
- Highlighting common laboratory errors that may lead to erroneous identification
- Emphasizing the value of review and validation of the microbial identification result
- Keeping abreast with taxonomy and nomenclature to fully understand the contaminant

Investigating mold contaminations
Mold contaminations are the least understood in the Pharmaceutical or Medical Device Industries. Often a contamination event is not discovered until it has made its presence known in the cleanroom or the product. Mold unlike bacteria has multiple methods of propagation; understand how these propagation methods may convolute traditional remediation efforts..

- Understanding the three major groups of mold found in cleanrooms
- Knowing how variants within each group differ in nature and structure

- Why fungal identification results could be misleading
- Common contaminants in facilities that can easily proliferate
- How different groups react to various disinfectants
- Points to consider when investigating mold contamination
- Why excessive cleaning and disinfection is not the solution

Investigating environmental monitoring excursions
The first step in investigating environmental monitoring excursions is to ensure that the excursion is not due to operator error, deviant airflow or media quality. Often alot of resources are expended in investigating excursions that are not due to the environment being out of control but due to unrelated reasons.
Learn how to identify true and false excursions and proceed accordingly with the investigation.

- Verify it is not an error
- Validate the microbial identification
- Separate excursions from out of specifications (OOS)
- Developing an action plan when an excursion occurs
    - Contaminant count, identification and objectionability
- Planning an investigation- information to be collected
- Impact of the excursion on product

Investigating sterility test and media fill failures

Investigations of sterility test and media fill failures must be thorough for ensuring product quality and patient safety.

- Discussion on aseptic media fills and sterility testing
- Similarities and differences between the two investigations
- Elements of Investigation for failed media fill runs and sterility test failures related to:
    - Facility and equipmet
    - Process
    - Personnel
    - Laboratory and training
    - Out of norm events

Investigation of microbiological out of specification (OOS) results

Understanding the difference between an excursion and a true OOS is the first step. Many laboratory errors may contribute to OOS in Microbiology. A step by step evaluation of laboratory techniques and differentiating a lab error from a true representation of risk to product.

- The root causes of microbiology laboratory errors
- Common causes of false negative and false positive test results
- Asspects of a thorough laboratory investigation
- Moving investigation from laboratory to manufacturing

Documenting investigations

- Common errors in conducting and documenting investigations
- Key points to consider when documenting facility and process related investigations
- Weeding out probable root causes from potential true causes
- Differentiating between remedial and corrective actions
- CAPA initiation and effectiveness

Assessing risk to patient-the main reason for investigations

- Understand the clinical relevance of particles as well as microbes depending on the mode of administration
- Learn about the factors to consider when determining objectionability of the contaminant to patient
- Learn about emerging and re-emerging pathogens for assessing the true risk to patient from the contaminated product

Registration Information

Personal Information of One Registrant	
Last Name:	First Name:
Job Title:	Organization:
Mailing Address:	
Telephone:	
Email:	
Fee: $1,850.00 per attendee, 2-4 10% discount and 5+ 20% discount (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 loechsli@microrite.com.

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. Kindly call 408-445-0507 in due time if confirmation is not received after payment.

Cancellation must be received 15 business days prior to the workshop less a 10% service fee, cancellation requests will be accepted via email only.

Payment Information

Choose One (Place X) ►	**___ VISA**	**___ Master Card**	**___ American Express**
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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.		

Speaker Overview

Ziva Abraham is the CEO and Founder of Microrite, Inc., a USA based consulting and training firm assisting companies globally. Our clients include pharmaceuticals, biotechnology, medical devices, other healthcare related industries and high technology manufacturing facilities. We strive to provide our clients with a comprehensive approach and unparalleled expertise in the areas of facilities, validation, microbiology, quality assurance and quality control.

Ziva has over 35 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 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.

Ziva Abraham

CEO

Microrite, Inc.

Morgan Polen is a subject matter expert on contamination control, airflow visualization and particle monitoring in cleanrooms with over 30 Years of experience in various industries. He is a member of the ISO Technical Committee 209 (Cleanrooms and Associated Controlled Environments) and a board member of IEST and has been instrumental in drafting and editing ISO 14644 and other cleanroom related standards. Well versed in the practical implementation of cleanroom standards, regulations and guidelines. A valuable resource in addressing contamination control in critical environments for the electronics, aerospace and healthcare industries. He possesses extensive experience in working on cleanroom projects across the globe and speaking on contamination control and pharmaceutical regulations for particle counting and environmental monitoring.

Morgan Polen

Contamination Control Expert

Microrite, Inc.