



microrite

**Mitigating Contamination Challenges in Cell Based
Regenerative Therapies**

1 Day Workshop

March 31, 2020

Baltimore, MD

Cell therapy and regenerative medicine technologies require strict cell manufacturing procedures to be defined and addressed. Maintenance of the aseptic environment is critical to preclude extrinsic contamination risks, similar to conventional pharmaceutical manufacturing. Intrinsic contamination risks exist in all cell manufacturing processes owing to the use of cells as the raw materials, which cannot be sterilized, thus giving rise to primary and secondary risks of cell contamination and cross-contamination, respectively.

The goal of contamination control in cell-based product manufacturing should be to map out the whole process and understand the risks for each step in the manufacturing operation. A comprehensive view of all of these elements, and anywhere there's an opportunity to mitigate contamination risk, including automation, is critical. Potential detrimental effects on the microbiological safety of any cell based products should be considered as high priority. A proactive contamination control mindset is critical.

This one day fast track intensive workshop will cover contamination issues from facility design to product release and how to develop a contamination control strategy. This will address, ATMP Guidance, EU Annex 1, EU Annex 2, FDA's Aseptic Guidance and more.

Which industries does this workshop apply to?

Cell Therapy, Gene Therapy, Tissue Banks and Wound Care products using live cells

Who will benefit?

Quality, Manufacturing, Research and Development, Facilities, Microbiology and Operators



March 31st, 2020- 8:00am to 5:00pm



University of Maryland BioPark 801 West Baltimore Street, Baltimore, MD, 21201



\$950 per attendee (group discount available: 2-4 attendees 10%, 5+ 20%)



Register at www.microrite.com



Email questions to info@microrite.com

Event Overview

Commonly encountered facility challenges

- Manufacturing facility design issues that are commonly ignored
- Isolator technology challenges related to design and integration
- Placement of barriers and equipment with inadequate airflows leading to repeat contamination incidents

In-coming materials

- Contamination challenges in incoming materials
- Difficulties in detection of contaminants in incoming materials

Extrinsic contamination

- Common extrinsic contamination sources
- Personnel, material, airflow and waste flow-the various contributors of extrinsic contamination
- Aseptic practices during multiple cell manipulations
- Incubator related contamination-a common occurrence

Disinfection challenges

- Choosing compatible disinfectants
- Developing a science based program to control extrinsic contamination
- Cleaning of BSCs and Isolators-common errors made
- Design flaws which hinder cleaning efficiency
- Developing a scientifically sound disinfectant qualification program

Human borne contamination

- Reasons why human borne contamination is predominant in cell processing
- Understanding gown choice, gown management and gowning procedures to control human borne contaminants during cell processing

Contamination detection

- Challenges in early detection of contaminated cells
- Learning growth patterns of different contaminants for timely detection

Testing challenges

- Gaps in sterility testing
- 483 observations related to sterility testing
- Causes of false positive and false negative sterility test results

Registration Information

Personal Information of One Registrant		
Last Name:		First Name:
Job Title:		Organization:
Mailing Address:		
Telephone:		
Email:		
Fee: \$950.00 per attendee, 2-4 10% discount and 5+ 20% discount (Includes 1-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:
<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 workshop date. For questions regarding payment methods feel free to contact Microrite at 408-445-0507 or send your enquiry to loechsli@microrite.com.</p>		
<p>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.</p>		
<p>Cancellation must be received 15 business days prior to the workshop less a 10% service fee, cancellation requests will be accepted via email only.</p>		

Payment Information

Choose One (Place X) ►	<input type="checkbox"/> VISA	<input type="checkbox"/> Master Card	<input type="checkbox"/> 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			
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.		

Speaker Overview

Ziva Abraham is the CEO and Founder of Microrite, Inc.

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.

Company

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

Consulting Services

Microrite, Inc. is 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. Visit www.microrite.com to learn more about us.