



Objectionable Microorganisms- Pathogen Specific Assessments

A part of Microrite's step-by-step webinar series

April 16th, 2020

1:30pm – 3:30pm (EST)

Online

1.5 to 2 hours including Q&A

The topic of objectionable organism is often discussed but defining what is objectionable is a challenge. From validating the microbial identification to assessing the true risk to the patient, there are many steps that require clinical microbiology knowledge and thorough research.

This webinar will provide guidance on the various steps involved before concluding that the contaminant is objectionable or not objectionable in the product.

Areas covered

- Regulatory perspective on objectionable organisms
- Why specified organisms per compendia are not the only organisms that may be objectionable in the product
- True pathogens vs opportunistic pathogens
- Understanding infective dose and virulence
- Knowing emerging and reemerging infections
- Understanding the increasing pathogenicity of microorganisms
- Going beyond compendia to establish objectionable microorganisms in various types of non-sterile products

Which industries does this webinar apply to?

Pharmaceuticals, Biotechnology, Medical Device, Cell/Gene Therapies, and Pharmacies

Who will benefit?

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

Speaker Overview



Ziva Abraham is the President and Founder of Microrite, Inc., a California based firm providing consulting and training services for medicinal product manufacturing. The team assembled by Ziva include; facility, airflow, particulate, sterilization, quality, validation and microbiology experts. Ziva's team participates in industry standards and guidance organizations (IEST, AAMI, ISO, ASHRAE, USP and IP) as board or expert committee members.

Ziva has over 35 years of clinical and pharmaceutical microbiology as well as mycology experience. She has received her master's degree in microbiology with a focus on Mycology and has conducted research on developing microbial Insecticides utilizing entomogenous bacteria and fungi towards her Ph.D. degree. Her career spans from founding and managing clinical laboratories for Maccabi Medical in Israel to working with pharmaceutical and medical devices companies.

As the principal microbiologist, and a part of her technical team, Ziva has helped large and small pharma, medical device, drug device combination as well as diagnostic companies. The roles varied from development of proactive contamination control strategies through pragmatic risk assessment, troubleshooting contamination issues and helping with FDA 483/warning letter remediation activities.

REGISTRATION FORM

Objectionable Microorganisms- Pathogen Specific Assessments**Registration Information**

Please register online at: <https://www.microrite.com/training/webinars/>

Fee: (see fee structure below, all costs are per person)

- ☐ 1 attendee **\$225**
- ☐ 2-5 attendees **\$180 (per person) (20% Discount)**
- ☐ 6 or more attendees **\$1,000 Flat Fee**

Method of Payment: Credit Card payments only. Attendees can register and make payments on Microrite's website: www.microrite.com. 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. 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.