



microrite, inc.
Airflow Visualization AKA "Smoke Studies"
For Pharmaceutical Manufacturing Cleanrooms
1 Day Intensive Seminar

Airflow Visualization AKA "Smoke Studies" for Pharmaceutical Manufacturing Cleanrooms
Bridgewater, NJ
May 21st, 2018

Perhaps the most misunderstood Cleanroom Test!!!

Airflow Visualization testing AKA Smoke Study is an extremely useful tool for preventing and remediating cleanroom contamination problems.

A significant portion of contamination related warning letters are due to inadequate airflows. These undetected airflows issues have led to:

- a. Major observations
- b. Issues related to EM and facility qualification and maintenance
- c. Questionable aseptic practices
- d. Data integrity
- e. Export bans
- f. Import holds
- g. Manufacturing shutdown

These can be prevented!

Airflow Visualization is a commonly misunderstood and many times poorly executed, which has led manufacturers to incorrect conclusions regarding airflow patterns within aseptic operations. Outdated technologies and poor understanding of unidirectional air flow prevent an accurate visual representation of airflow in sterile, aseptic and low bioburden cleanrooms.

Airflow Visualization (AFV) when properly done with the correct technologies is an important tool to evaluate the actual air flow patterns.

Learn from the experts who are helping resolve these issues, which if detected upfront would have saved companies a lot of grief.

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, Engineering and Training

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AGENDA

May 21st, 2018	Hilton Garden Inn in Bridgewater NJ 500 Promenade Boulevard Bridgewater New Jersey, 08807 Tel: 732 271 9030
Agenda	
Registration and Breakfast	8.00 AM to 8.30 AM
<ul style="list-style-type: none">• Demonstration of Technologies used in AFV studies• Example Videos of actual AFV studies	8:30 AM to 10:00 AM
Break	10:00 AM to 10:15 AM
<ul style="list-style-type: none">• FDA's expectation related to airflow visualization• AFV criticality to ensure aseptic practices• ISO 14644 requirements for smoke studies• Other guidance's on smoke studies	10:15 AM to 12:00 PM
Lunch	12:00 PM to 12:45 PM
<ul style="list-style-type: none">• Myths and facts about AFV- where the mistakes are made• More airflow and air exchange rates does not guarantee asepsis• Common cleanroom, RABs and isolator design and integration flaws that lead to contamination issues	12:45 PM to 3:00 PM
Break	3:00 PM to 3:15PM
<ul style="list-style-type: none">• Discussion on AFV related 483s that Microrite has help remediate• Precautions to be taken to avoid these pitfalls	3:15 PM to 4:30PM
Questions and Answers and discussions	4.30 PM to 5.00 PM

Hotel Recommendations:

Hilton Garden Inn in Bridgewater NJ- 500 Promenade Boulevard, Bridgewater New Jersey, 08807

*Microrite does not have a room block at any hotel

Airport:

Newark Liberty International Airport (EWR)

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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: \$900.00 per attendee (Includes 1 day workshop fee, breakfast, lunch, break, and course material)

Additional Attendees

First Name:	Last Name:	Title:
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First Name:	Last Name:	Title:
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First Name:	Last Name:	Title:
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First Name:	Last Name:	Title:
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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) ▶	<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(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

Morgan Polen has been involved with cleanrooms and contamination control since 1984. He has worked in over 40 countries involved with projects ranging from cleanroom design, construction, validation, AFV, monitoring program development, particle counter design and product management for cleanroom related products and systems. He has addressed monitoring and control solutions in a wide variety of clean industries such as pharmaceutical, medical device, semiconductor, data storage, aerospace, defense, automotive, optical and others. Morgan is a member of IEST's US Technical Advisory Group to ISO/TC 209 Cleanrooms and Associated Controlled Environments, participating in the process of adapting the latest cleanroom standards.

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

Visit www.microrite.com to learn more about us