



**Myths, Mistakes and Misunderstandings Related To Airflow
Visualization(Smoke Studies)**

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

May 5th, 2020

1:30pm – 3:30pm (EST)

Online

Why should you attend – Why is it important to learn about the topic

Airflow visualization is a science not unique to the pharmaceutical industry. Airflow visualization and air pattern analysis have been utilized by many industries in order to characterize airflow patterns. As air is invisible, the behavior of tracer particles added to the airstream are observed, recorded and analyzed.

It is important that the tracer particles faithfully follow the air patterns and the documentation methods are suitable.

The multitude of FDA 483 observations and warning letters citing data integrity for; environmental monitoring, media fill and product sterility testing data begins with poorly executed airflow visualization studies (smoke studies).

The increased scrutiny by regulatory agencies regarding smoke studies is indicative of regulator's lack of confidence in outdated approaches to contamination control as well as concerns over aging facilities and obsolesced systems.

The "c" in cGMP stands for current and per the FDA; "systems and equipment that may have been top of the line to prevent contamination, mix-ups, and errors 10 or 20 years ago may be less than adequate by today's standards."

This training will address the common errors and misunderstanding related to smoke studies, specifically addressing updated regulator thinking.

Areas Covered in the Session:

- The science of airflow visualization
- Current regulatory perspective on smoke studies (Draft GMP Annex 1 2020 update)
- Case studies and 483 observations related to smoke studies
- Myths and mistakes related to "in-situ air pattern analysis"
- Common mistakes made that lead to 483 observations
- Data integrity related smoke studies; a common phenomenon

Which industries does this webinar apply to?

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

Who will benefit?

Quality Assurance, Quality Control, Microbiology, Manufacturing, Engineering, Facilities, Validation, and Training Personnel

Speaker Overview



Morgan Polen: Cleanroom, Particulate and Airflow Expert at Microrite, Inc.

Morgan Polen is a subject matter expert on contamination control, airflow visualization and particle monitoring in cleanrooms with over 30 Years of industry experience.

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. He has extensive experience in working on cleanroom projects in the United States, Canada, Mexico, Germany, Malaysia, Taiwan, South Korea, Singapore, Thailand, China, Philippines, India and Turkey and is a valuable resource in addressing contamination control in critical environments for the electronics, aerospace and healthcare industries.

As a key member of Microrite's Expert Contamination Control team, Morgan is instrumental in development of proactive contamination control strategies through pragmatic risk assessment, troubleshooting contamination issues and helping with FDA 483/warning letter remediation activities

REGISTRATION FORM

Myths, Mistakes and Misunderstandings related to Airflow Visualization(Smoke Studies)

Registration Information
Please register online at: https://www.microrite.com/training/webinars/
Fee: (see fee structure below, all costs are per person)
<input type="radio"/> 1 attendee \$225 <input type="radio"/> 2-5 attendees \$180 (per person)(20% Discount) <input type="radio"/> 6 or more attendees \$1,000 Flat Fee
<p>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.</p>
<p>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.</p>