



# microrite

**The Science Behind Smoke Studies**

A part of Microrite's **complementary** webinar series

April 7<sup>th</sup>, 2020

11:00am EST to 12:00pm EST (Duration: 1hr.)

**Free Online Training**

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

The increasing number of FDA 483 observations related to smoke studies eludes to a gap in understanding the science, methodology and the purpose behind this important contamination control tool. Airflow visualization is a science not unique to the pharmaceutical industry. The purpose of smoke studies is to characterize and map airflows to detect any deviant or questionable airflow patterns.

These myriad smoke study related observations are indicators of the regulator's suspicion of contaminated product or data integrity. The recent scrutiny regarding airflow visualization reflects a more astute regulatory body that understands the effect of cleanroom design and airflow on product quality.

Airflow visualization has evolved from a simple test with some videos to becoming a critical component of a holistic contamination control strategy. Airflow visualization, if executed and documented correctly, provides a tool to optimize the contamination control effect of clean air in conjunction with material and operator movements.

This session will dissect recent regulator's comments and observations and explain why the technology and methodology are crucial for detecting inappropriate airflows.

## **Topics Covered in the Session:**

- Reasons behind smoke study related 483 observations
  - Smoke quality
  - Smoke density
  - Smoke dissipation rate
  - Camera angles
  - Incomplete or partial study
  - Inconclusive reports
  - Video quality
  - Unavailability of video documentation
- Smoke study technology
- Tracer particles and importance of neutral buoyancy
- Tracer particle ejection methodology and velocity
- In-situ air pattern analysis
- Post smoke study cleaning; "there is nothing clean about SMOKE study"

## **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

## **Registration information:**

Kindly register online at <https://www.microrite.com/training/webinars/>, email [webinars@microrite.com](mailto:webinars@microrite.com) for assistance.

## 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.*

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**Bill Shade:** Sr. Engineer/Particle Technology Expert at Microrite, Inc.

*Bill possesses extensive engineering experience in advancing of particle counting technology through innovative product design and project management resulting in full product development life cycles. His engineering background includes applications, systems, optical and electrical design. Bill has broad experience in troubleshooting particle counting / generation devices as well as configurations including particle monitoring systems and smoke generating devices. He has developed new technologies in particle monitoring science; he has also created innovative optical designs of high flow particle counter sensor using a refractive mirror resulting in the smallest high flow particle counter sensor design to date.*

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