



Microrite, Inc. brings you this unique learning experience in Air Flow Visualization (Smoke Study) Techniques and Technology; Part of Microrite's step-by-step webinar series.

Air Flow Visualization (Smoke Study) Techniques and Technology A Risk Based Approach

Understanding airflow patterns in cleanrooms and controlled environments is an important aspect in contamination control. Personnel, equipment and material flow can influence airflow and affect contamination levels in even the most well designed cleanrooms. Air flow visualization studies, sometimes referred to as smoke studies are useful in providing a visual representation of air flow in cleanrooms. These tests can also be useful in troubleshooting cleanroom contamination issues resulting from undetected air patterns that limit a cleanrooms ability to provide adequate contamination control. Airflow Visualization is an expected test by pharmaceutical inspection authorities and mentioned in FDA, PIC/S and USP guidance documents. Many companies have faced regulatory scrutiny based on their facility airflows; conversely many have resolved underlying issues after conducting a risk based airflow visualization study.

The criticality of airflow must not be understated when considering critical operations such as aseptic manufacturing. Because of this, the type of equipment and material used in creating the airflow visualization vapor or smoke is as important as the techniques used. As these tests require the use of Tracer Particles, the material and size of these Tracer Particles and method of injecting them into the airflow is an important consideration. The Tracer Particles should be of suitable size and volume as to visually represent the air moving through the cleanroom or clean space being tested.

Microrite's unique approach and methodology have assisted many companies in resolving their underlying facility and process issues, subsequently establishing and implementing an effective contamination prevention and control strategy.

When?

February 19th, 2018
9:00 am to 10:00 am
India Standard Time

Which industries does this webinar apply to?

Pharmaceuticals, Biotechnology, Medical Device, API manufacturers, Nutraceuticals and Cosmetics

Who will benefit?

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



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What will be covered:

Improperly conducted air flow visualization studies or the use of equipment that may not be suitable for conducting these studies may lead to misleading conclusions related to airflow in critical areas. As the various pharmaceutical inspection authorities expect these studies to be conducted under dynamic conditions, as simulations of actual processing operations, it is important to understand the complexities related to doing dynamic smoke studies. This presentation will discuss the various methods and techniques of air flow visualization as well as provide examples of improperly tested facilities including FDA 483 Observations and warning letters related to airflow visualization.

Who will be teaching?

Morgan Polen has provided cleanroom and contamination control solutions since 1984, working in over 40 countries. His projects include, identifying contamination sources and regulatory discrepancies in areas such as; cleanroom design, construction, validation, monitoring program development and sampling. Morgan has additionally participated in particle counter design and product management for cleanroom related products and systems. Morgan has provided consultation to companies 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 United States Technical Advisory Group ISO/TC 209 Cleanrooms and Associated Controlled Environments. Participating in the process of adapting the latest cleanroom standards.



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Additional Attendees		
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