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Air Flow Visualization Study Strategy used by Microrite:

An Air Flow Visualization Study (sometimes referred to as smoke study) with video documentation can provide a visual indication of airflow in cleanrooms. It is useful in identifying eddy currents and recirculation of air flow as a means of assessing risk of contamination in critical areas within a cleanroom. This is an expected test by pharmaceutical inspection authorities and is also a very useful in troubleshooting cleanroom airflow problems in any cleanroom. In medical product cleanrooms, the FDA, EMA, PIC/s and the WHO require documented air pattern analysis with written conclusions, including the effects of aseptic interventions in critical areas.

It is important to evaluate air flow patterns to assure that these patterns do not pose a risk of distributing particles from sources such as the surrounding environment, personnel, operations, materials or equipment. These tests are used to demonstrate that airflow under dynamic (operational) conditions does not contribute to contamination risk.

Microrite's strategy for conducting smoke studies includes:

- Use of adequate equipment
- Tracer particle of correct bouyancy and longevity to correctly visualize the **actual** airflow patterns
- Use of multiple cameras to capture the risk associated with eddy currents and deviant airflow patterns
- Use of particle measurement in conjunction with smoke study to identify critical control points
- Simulation of equipment setup and assembly, aseptic connections, operations, transferring of components and product, as well as environmental monitoring and interventions to understand their effects on the actual airflow patterns
- Diagnose the effects of surronding environments on critical areas
- Documented evidence of airflow patterns with recommendations

Benefits of using this strategy for conducting smoke studies include:

- Identify barrier technology or critical environment design issues
- Prevent environmental monitoring excursions, media fills and product failures by identifying eddy currents and deviant airflow patterns which can be corrected and properly monitored to address risk
- Prevent data integrity issues by identifying and correcting poorly designed, constructed, maintained and integrated cleanrooms and barrier systems
- Determine if gowning strategies and practices are adequate to support operations in conjunction with facility and barrier system design and integration
- Evaluate aseptic manipulations and techniques in relationship to airflow patterns

How we work

Microrite requests cleanroom design drawings, photographs as well as cleanroom qualification reports. Also requested are the type and number of interventions to be simulated during dyanamic smoke studies.

Once a commitment is made by the client after executing a non-disclosure, Microrite shares a smoke study protocol which is then filled out by the client with the rooms, activities, interventions and other details related to the study.

Prior to conducting an in-situ dynamic airflow study, a static smoke study is performed to investigate cleanroom and barrier system integration and associated airflows.

Simulation of set-up and assembly, manufacturing operations, environmental monitoring and interventions during dynamic smoke study helps identify the effect of environment, materials, and personnel on the operations.

After executing the static and dynamic smoke study:

- The video data is transferred to the customer on the original media
- A report is generated which includes:
 - References to various original video files
 - Documented evidence based upon risk that evaluates airflow patterns
 - Conclusions addressing specific FDA and EMA/PICs expectations related to Air Flow Visualization Studies
- A summary video documenting operations utilizing multiple cameras is provided

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