

PURPOSE OF AIRFLOW VISUALIZATION/SMOKE STUDIES

- Is to provide a visual representation of the ACTUAL air flow patterns in cleanrooms

ERRORS IN AIRFLOW VISUALIZATION/SMOKE STUDIES ARE CAUSED BY

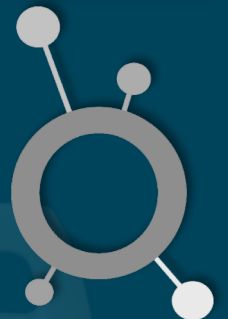
- Inadequate equipment (water based, CO₂, and Liquid Nitrogen)
- Produces a fog that is heavier than air that drops out of the air stream or dissipates too quickly can not map the ACTUAL air patterns in cleanrooms
- Lack of training/understanding of Contamination Control principles related to air flow in cleanrooms

AIRFLOW VISUALIZATION/SMOKE STUDIES ARE REQUIRED BY REGULATORY BODIES

- GMP Annex 1 and FDA Sterile Guidance 2004 as part of Initial Qualification and repeated on regular intervals based upon risk assessment or changes in the manufacturing line.
- USP 797 As part of initial qualification and repeated every 6 months or changes in the manufacturing area.

CONSEQUENCES OF IMPROPERLY PERFORMED AIRFLOW VISUALIZATION/SMOKE STUDIES

- Improperly qualified Manufacturing Facilities (Turbulent or Refluxing Air Flow in Aseptic Areas)
- Environmental monitoring excursions
- High bio burden and product failures
- Observations from regulators
- Warning letters
- Product recalls
- Data Integrity



WHY MICRORITE?

- Microrite's state of the art equipment, sub-micron buoyant tracer particles and methods visualize actual airflows in cleanrooms and barriers, identifying any possible risks of contamination and optimizing Environmental Monitoring Locations.
- Multiple cameras and quad view video reports highlight contamination sources which can be corrected or monitored
- Data integrity proof reporting for sharing with regulators