

# Smoke Studies & Correlation with GMP & EM sampling location

**Multi Angle Static and Dynamic Smoke Study** is not only an evidence of unidirectional airflow movement but also it is a very good tool for auditors to review **GMP practices**.

With **360 Degree Multi Angle Static and Dynamic Smoke Study**, the videos will provide many different views and **close-up views** within the sterile core area (Aseptic filling line) that are not visible or clearly visible through the view windows or handy cameras into these areas. **(Refer the Picture -Close View)**

The advancement in videography technology enable to capture very clear and close views which was not possible earlier.



These clear and close views can identify **GMP issues** for a regulatory inspector.

It is also very efficient tool for QA team to review and to train personals for **GMP practices**.

## Smoke Study & GMP:

- **Aseptic technique:** A clear view of the aseptic technique used in complex interventions could lead to further review of the technique for reproducibility as practiced currently.
- **Gowning:** When viewing the condition of gowning and compliance with gowning requirements, any differences with current gowning practices will be evaluated.
- **Cleaning & Sanitization:** A view showing the facility and equipment complexity of design, age, and surface condition (e.g., excessive number of scratches or deep scratches/gouges, deterioration, rust) can lead to questions about how these surface conditions may impact the ability of

current practices to consistently and effectively clean, sanitize, and sterilize these surfaces.

- **Preventive Maintenance:** Questions about preventive maintenance and part replacement practices in these critical areas may also be pursued.
- So, QA review of the smoke studies should not be limited to airflow issues but to the entire content of the video to ensure all GMP issues have been addressed, including those not directly related to airflow.

## Smoke Study & EM Sampling location:

**USFDA 483(Observation):**

- ✓ You do not have a scientific rationale for the environmental monitoring sampling locations in aseptic filling Suites (b)(4). You did not include factors such as smoke study findings, number and location of operators, and historical microbial data in your assessment of hazardous points.
- ✓ For example, we found that settling plates are not appropriately placed in critical areas. Your smoke study showed that during set-up and filling, air flows toward the front (when the (b)(4) is open) or back of the RABS. However, two relevant sampling points were recently eliminated. As a result, these points of increased risk are not monitored.

While deciding the EM Sampling location, Smoke study is one of the major factors, we have to take into consideration. It is important because smoke study gives an idea of the path, the contamination will follow.

**The Solution:** As a GAMP Group , We provide Comprehensive Smoke Study Services which includes 360 Degree Multi Angle Smoke Study Project Execution, CFD Project Execution & Consultation & Smoke Study Remediation Projects.

**We provide complete turnkey smoke study solution consisted of**

- Protocol
- Execution
- Data Processing
- Review & Report
- CFD
- Review of HVAC, Barrier System & Filling Line
- Remediation Project
- Experienced team of 200+Filling line execution

**Multi Angle Smoke Study-  
360 Degree VIEW**

