

# A SMOKE STUDY “DELIVERS MORE THAN EXPECTED” AT A MAJOR PHARMACEUTICAL MANUFACTURER IN COLORADO

## AT A GLANCE

A major pharmaceutical manufacturer near Fort Collins, CO required a team of skilled and experienced professionals to complete a smoke study within their aseptic syringe filling suite.

## Services Provided

- Planned and Executed the Smoke Study
- Development of protocol including reviews, revisions, and approvals
- Daily review of raw footage with stakeholders
- Creation of final videos for presentation to auditors
- On-site instruction for Aseptic Operators



### DELIVERED

final videos and smoke study results within a tight deadline



### EDUCATED

client and operators on proper CAV execution



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## DIFFERENT APPROACH TO FIT CLIENT'S NEEDS



When Performance Validation (PV) initially met with our client; they stressed the importance of requiring a team of experts to carry out the project. They did have one team member who could implement the smoke study; however, they understood it would take a larger team to carry out the mission properly. By choosing to partner with PV and our subject matter experts (SMEs), our client felt confident they would receive a more detailed and thorough study than they have received in the past.

During the planning stage, after reviewing the client's previous smoke study videos, it was clear that large portions of the process were skipped, therefore our SMEs knew a standard approach would not suffice because it didn't sufficiently analyze the aseptic interventions. Therefore, our team developed a tailored solution, which would not only cover the missing areas, but would provide our client with the complete and proper documentation for internal auditors and regulators.

## DAILY REVIEW WAS KEY FOR SUCCESS



The client had an important request to review the smoke study footage daily. While a daily review was not a standard PV procedure, our team was happy to comply with the request. The PV team downloaded the footage nightly and scheduled morning meetings with the client's quality and validation teams to review for any findings that required attention before filming resumed. After addressing several findings from the operator's processes which needed correction, PV SMEs requested to stop filming and continue the project by running scenes prior to turning on the cameras. This allowed our experts to share their extensive experience and knowledge with aseptic lines and smoke studies to explain how certain steps should be executed and how airflow was affected when not executed properly, including process flow and operators' movements that were affecting the aseptic line airflow. This approach helped the client to improve its process during the execution of the critical airflow visualization study.

After experiencing the benefits from the daily footage, PV SMEs can recommend the daily review as a best practice for future airflow visualization projects.

## Phase 1

Protocol approval and development of execution script



## Phase 2

On-site set up and video recording



## Phase 3

Daily revisions, manufacturing process corrections and operator training



## Phase 4

Postproduction processing, creation of final videos from raw footage



## Phase 5

Deliver final videos and report



Critical Airflow  
Visualization Services



Project  
Management

### PERFECT OPPORTUNITY



Our SMEs knew from the previous footage provided by the client there would be challenges getting the smoke in the proper places. While adding a second large fogger during the smoke study was also a first-time element for the PV team, we were confident this would allow our team to film the process from contrasting different angles to provide sufficient examination of the critical airflow. The smoke helps people to visualize the airflow and understand how the proper execution of procedures, or deviations of the standard procedures, can affect the airflow, making the smoke study an excellent opportunity to train teams working on the daily operations of the aseptic line improving the process and minimizing quality risks.

Utilizing our thorough and meticulous approach and adding the second fogger played a crucial role in delivering a high-quality airflow visualization video and a precise final report.

### CLIENT BENEFITS FROM NEW PROCESSES



PV approaches each project as an opportunity to provide tailored, innovative ways to offer the best service and solutions to our clients. The extensive experience and knowledge of PV's SMEs executing smoke studies, allowed our team to make crucial decisions and improvement suggestions during the planning and execution phases that improved the study's quality and result. By taking the extra steps of adding a second fogger and additional cameras, PV was able to provide a more thorough and complete smoke study within the client's timeframe.

### PROJECT SUMMARY



Our client partnered with PV to help with their compliance. They wanted a team of experts to come in, set up their equipment, and provide a smoke study for their aseptic syringe filling suite. While we found several areas that were overlooked during previous smoke studies, PV was confident they could provide the right solutions for our client. Our experts took the time to educate and provide additional training for operators to help them fix their processes. PV was able to meet all the expectations and deliver the smoke study results within the tight deadline.

### WE TURN CRITICAL INTO COMPLIANT



Since 1988, Performance Validation has been providing clients with expertise in the commissioning, qualification and validation service areas in the life science industries. Our team thrives on the importance of quality, integrity and teamwork, giving our clients peace of mind during every step of the project.



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