

# CONDUCTING A TOP-TIER SMOKE STUDY IN TWO DAYS FOR A CRO'S FILLING LINE

## AT A GLANCE

A leading contract research organization (CRO) and full-service cGMP manufacturer (CMO) in Bloomington, IN, installed a brand-new filling line to package pharmaceutical products for its customers.

The filling line needed to undergo a smoke study to meet regulatory requirements. With an FDA audit approaching quickly, the CRO partnered with Performance Validation (PV) to ensure the project was completed on time and within budget.

## SERVICES PROVIDED

- Project Management
- SOP Development
- Smoke Study Protocol Development & Execution
- Critical Airflow Visualization Services
- Final Report Generation & Approval

## A FASTER, LESS EXPENSIVE WAY TO DO SMOKE STUDIES



In the pharmaceutical industry, the FDA requires the auditing of smoke study videos to ensure airflows are correctly assessed. For years, the standard practice was to manually record a smoke study on camcorders and then synchronize the footage afterward. This process was time-consuming and prone to errors.

Thanks to technological advancements, PV developed a new smoke study process that involved livestreaming from four cameras simultaneously. This eliminated post-production, saving time and money.

Here are the steps PV took to complete the smoke study for the CRO in Bloomington:

- **Developing the SOP:** PV helped the CRO develop its Standard Operating Procedure (SOP) to outline the entire smoke study process.
- **Creating the Qualification Protocol:** Using the SOP, PV developed the qualification protocol, detailing what would be tested and how testing would be conducted.
- **Shipping Equipment:** Once a test date was scheduled, PV shipped all necessary equipment to the CRO's facility, which included large crates of testing gear.
- **Equipment Cleaning:** Before bringing equipment into the clean space, PV thoroughly wiped everything down to ensure cleanliness.
- **Setting Up:** PV set up the fog curtain, fogger, cameras and cables in this specific order to prevent unnecessary rework.
- **Pre-Approval of the Protocol:** Before proceeding, the CRO reviewed and signed off on the protocol.
- **Filming the Smoke Study:** Operators donned their cleanroom gowns and performed the smoke study.
- **Post-Test Wrap-Up:** PV dried the equipment, packed it up, shipped it out and wrote the final report. The report was reviewed with the CRO before final sign-off.

The PV team completed the smoke study project in two days thanks to their focus and fast execution.



During the project, PV encountered several obstacles related to limited space, scheduling conflicts, and the need for a fast turnaround. The PV team used their expertise to remain flexible and efficient during the engagement, ensuring the filling line was audit-ready.

### GETTING EFFICIENT IN TIGHT SPACES

One major challenge PV faced was working within a confined space while ensuring a smooth and effective smoke study. The setup required four cameras, one fogger, two operators, and multiple observers, all operating in the same area. With limited room to maneuver, there was a constant risk of shuffling around equipment, tripping over cables, and obstructing views.

The PV team's experience in these environments allowed them to adapt quickly. They utilized physical strategies and specialized techniques to optimize the workspace, minimizing disruptions while maintaining clear sightlines for filming.

For example, one key advantage was PV's camera rigging expertise. If a camera needed to be positioned in a precise location, PV had the necessary mounting and rigging equipment to make it happen, ensuring that every critical angle was captured effectively.

By implementing these space-saving techniques and efficient setup strategies, PV successfully conducted the smoke study without compromising visibility, safety, or data quality.

### STAYING ON TRACK THROUGH SCHEDULING DELAYS

Scheduling the smoke study proved challenging because the filling line and cleanroom were newly constructed, and ongoing construction delays made it difficult to establish a firm testing timeline. As a result, PV had to stay agile and adaptable throughout the process.

To overcome these challenges, PV maintained open and continuous communication with all stakeholders, ensuring they were always aware of the latest developments. By staying flexible and responsive, PV was able to adjust plans in real time, quickly rescheduling as needed while minimizing downtime. This proactive approach ensured that the smoke study was completed at the right time without disrupting the facility's progress, keeping the project on track.

## EQUIPMENT USED

- CRF6 WFI Cleanroom Fogger
- 4 Cannon 4K Camcorders
- PC with Samsung External Hard Drive
- 4 External LED Light Panels
- Black Backdrop
- Custom Wand with Dispersion Curtain

