EXCEEDING EXPECTATIONS: VOLUNTARY CLEANROOM AIRFLOW ASSURANCE AT A 503A COMPOUNDING PHARMACY

AT A GLANCE

A leading 503A compounding pharmacy in Texas engaged Performance Validation (PV) to perform a comprehensive Critical Airflow Visualization (CAV) study across 21 cleanroom areas—including downflow booths, biosafety cabinets, personnel airlocks, and a high-speed filling line. Although U.S. regulations do not require 503A facilities to conduct smoke studies, the client sought to surpass standard expectations, proactively documenting airflow performance to protect patient safety and product integrity.

SERVICES PROVIDED

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

A QUALITY-DRIVEN OBJECTIVE BEYOND REGULATORY REQUIREMENTS

Unlike traditional pharmaceutical manufacturers, 503A compounding pharmacies are governed by a different set of regulations. Operating under Section 503A of the Federal Food, Drug, and Cosmetic Act, these pharmacies prepare patient-specific medications based on individual prescriptions and are typically overseen by state boards of pharmacy rather than the FDA. Because they do not manufacture drugs for mass distribution, they are not required to follow FDA Current Good Manufacturing Practices (CGMPs) or conduct airflow visualization studies as part of their routine operations.

Despite this, the pharmacy's leadership made the deliberate decision to validate airflow patterns throughout their cleanroom environment. Their goal: to meet or exceed the standards typically applied to large-scale GMP facilities. This proactive move required a temporary facility shutdown, coordination across multiple departments, and a significant financial investment—actions that underscored their internal commitment to operational excellence, product integrity, and patient safety.

AROUND-THE-CLOCK EXECUTION, DELIVERED TWO DAYS EARLY

To accommodate a facility-wide shutdown and an aggressive project timeline, PV deployed a six-member team operating in alternating day and night shifts. The original schedule called for nine full days of smoke study execution across 21 rooms. However, thanks to meticulous planning and highly coordinated execution, the project was completed in just seven days, saving the client two full days of downtime and enabling a faster return to production.

This efficiency was not accidental. The client played a key role in the project's success by ensuring that every gowning set, cleanroom component, equipment part, and test location were fully prepared and staged before PV's arrival. This level of internal readiness is uncommon and eliminates the typical slowdowns caused by missing materials, unavailable water, or unwrapped components. According to PV's field team, it was one of the most efficient CAV studies they have ever executed, largely due to the client's proactive communication, well-briefed staff, and culture of operational discipline.

With minimal idle time between test areas and no need to revisit any rooms due to setup issues, PV's team was able to move through the entire scope of work quickly and confidently. The early completion not only reduced disruption to the pharmacy's operations but also enhanced overall satisfaction among internal stakeholders eager to resume compounding activities.

CUSTOM PROTOCOLS AND HIGH-DEFINITION MULTI-ANGLE FOOTAGE

PV developed and finalized the project's testing protocol in close collaboration with the client, adapting it to meet their internal documentation standards while ensuring that each airflow visualization aligned with best practices. Our subject matter expert revised and refined the protocol to reflect the unique requirements of 21 different cleanroom spaces, including complex areas such as biosafety cabinets and a high-speed filling line.

Testing was performed using a WFI fogger and PV's multi-camera wireless video system. The setup included four professional-grade Canon cameras and portable LED lighting, enabling high-definition capture from multiple angles. Our field team implemented creative lighting techniques to enhance smoke visibility, particularly in areas where ambient conditions posed a challenge.

Unlike typical smoke study setups that rely on low-resolution action cameras, PV's system delivers crisp, quality footage designed for audit-readiness. Built on modern wireless technology and optimized for cleanroom environments, the resulting videos provide clear documentation of airflow direction, unidirectionality, and potential turbulence—giving clients, auditors, and internal stakeholders full confidence in the results.

RAPID TURNAROUND SUPPORTS FASTER RETURN TO PRODUCTION

Following the successful completion of testing, PV delivered the final edited video footage and comprehensive report the very next morning—enabling the client to resume operations without delay. This rapid turnaround was made possible in part by PV's advanced Livestream video system, which captures four simultaneous camera angles and allows for real-time review. With synchronized, high-definition footage already in hand, PV's team was able to complete post-processing and documentation while still on site.

Unlike the industry norm, where video compilation and reporting may take weeks, PV's streamlined approach ensures that clients receive audit-ready deliverables immediately supporting compliance efforts, accelerating internal approvals, and reducing overall downtime.