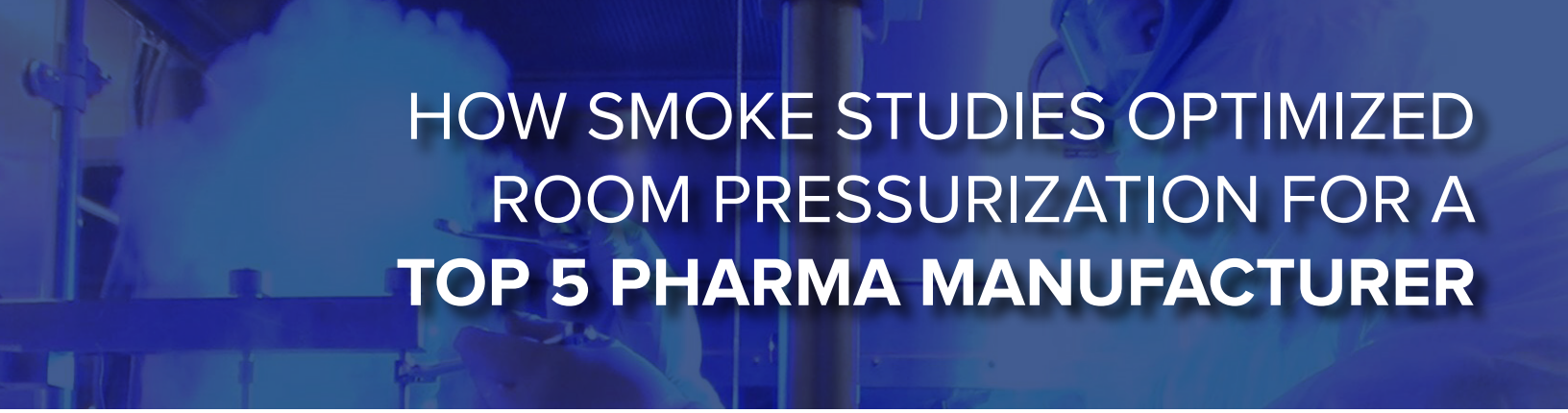

HOW SMOKE STUDIES OPTIMIZED ROOM PRESSURIZATION FOR A **TOP 5 PHARMA MANUFACTURER**

AT A GLANCE

A top 5 pharmaceutical manufacturing company in North Chicago, Illinois, partnered with Performance Validation (PV) to perform smoke studies in a building with 14 different areas for packaging, filling, mixing, and bottling. For each area, the team conducted three scenes: a baseline, a material airlock examination, and a personnel airlock examination.

The main project goal was to ensure operator safety. In areas with potent products, such as packaging rooms, the pharmaceutical manufacturing company wanted to ensure its operators were not contaminated with any drug substances. To do this, the PV team examined the ability of certain packaging rooms to provide containment of a product for a specified amount of time when a door is held open.

PV Performs Comprehensive Smoke Studies to Challenge Room Pressurization Alarms

In pharmaceutical manufacturing, audits occur regularly to ensure compliance, quality and safety standards are met. If the auditor finds an issue, the company must investigate the root cause of the problem, implement corrective and preventive actions (CAPA) and provide documentation to demonstrate how they are addressing the issue.

When an auditor visited the pharmaceutical manufacturing company and challenged the delay times on the room pressurization alarms, the pharmaceutical company did not have any data to back up the current 10-minute timer. The pharmaceutical company needed to provide evidence that the timer was scientifically justified and effective in maintaining the required level of containment and compliance with regulatory standards.

As part of the Corrective and Preventive Action (CAPA) response, the pharmaceutical manufacturing company partnered with PV for smoke studies to provide data to support the optimal alarm delay time. These studies aimed to evaluate and document the actual containment capabilities and effectiveness of the pressurization systems.

The PV team set up four cameras in each room to observe how the emitted fog reacted when the door opened and stayed open. They introduced fog into the normal production area to verify if the fog could be contained for 10 minutes, which was the duration of the delay on the in-house alarms.

The team used water for injection (WFI) fog technology for this project because the clean water created fog that didn't leave behind residue. One of the challenges of using the WFI fogging technology was the lower residence time compared to propylene glycol fog technology. This made it more challenging to see and maintain visibility over extended periods. The PV team introduced a black backdrop to make it easier to see the fog on camera.

As a result of the smoke study, several of the in-house alarms were changed to less than 10 minutes because many of the rooms were unable to prove 10 minutes of containment.

Services Provided

- Protocol Development and Adherence
- Video Production
- Critical Airflow Visualization Services
- Document Development
- Camera Setup and Positioning
- Efficient Use of Placards
- Used Adaptive Execution Process
- Ensured Compliance and Quality
- Tailored to Each Client's Unique Needs

Overcoming Physical & Technical Challenges

PV experienced various physical and technical challenges throughout the project. With determination and flexibility, the PV team was able to overcome the obstacles and lead the project to success.

Challenge #1: WFI Fog Visibility

By nature, WFI fog was hard to see with the naked eye. WFI fog created a cold, humid cloud through sonication. Ultrasonic waves produced tiny droplets of water that dispersed quickly into the air, meaning WFI fog was only visible for a short time. While glycol would have been easier to see, the pharmaceutical manufacturing company requested WFI fog to keep the packaging areas clean.

PV collaborated with the pharmaceutical manufacturing company to develop testing procedures that met its specific needs. To enhance the visibility of the WFI fog during testing, the team utilized a black backdrop. This dark background made the fog more visible against the contrast, improving the clarity of observations. Additionally, lights were used to illuminate the fog, further enhancing visibility and allowing for accurate monitoring and analysis.

Challenge #2: Varied Room Sizes

The pharmaceutical manufacturing company's facility had rooms ranging from vast spaces of hundreds or even thousands of square feet to very small rooms where the usual testing setup was impractical.

To set up the testing environment in the larger rooms, PV installed a black backdrop, positioned four cameras and deployed up to four foggers. Each component had to be carefully managed and synchronized to ensure accurate results. Despite the extensive setup, PV effectively managed the complexity by meticulously organizing the equipment and using a systematic approach to ensure consistency across the different room sizes.

The smaller rooms presented a different challenge. With space constraints that only allowed for one person to work at a time, PV adapted by having team members take turns conducting the tests. This rotation ensured that the testing could proceed without compromising the quality of data collection or safety.

Challenge #3: Electricity

The PV team required about 40 amps of electricity to operate the equipment, but the rooms they were working in were equipped with only 15-amp outlets. This discrepancy posed a potential risk of overloading the electrical system and could have interrupted the testing process.

To overcome this challenge, PV leveraged its foresight and preparation. The team had anticipated potential electrical constraints and brought all necessary equipment, including extension cords and power strips, to the site. The team utilized these tools to run power from the hallway and into adjacent rooms, effectively bypassing the inadequate outlet in the testing room.

By carefully managing the power distribution and ensuring that all electrical connections were secure and properly rated, PV successfully provided the required 40 amps of electricity without compromising safety or efficiency.

Challenge #4: Production Outages

To conduct the tests accurately and safely, the rooms could not have any live product or active production. This requirement necessitated flexible scheduling to avoid disrupting the manufacturing process.

PV overcame this challenge by meticulously coordinating its testing schedule with the pharmaceutical company's production timeline. The team demonstrated remarkable flexibility and adaptability, making six separate trips to the facility to accommodate the various production lines. This approach ensured that each smoke study could be performed without interfering with ongoing manufacturing activities.

Challenge #5: Project Videos

Creating final videos after executing smoke studies posed a unique challenge for PV. Normally, the team would physically mail a USB drive to the client, but in this case, the stakeholders preferred the videos to be uploaded to the cloud. This improvement from the standard procedure was necessary because the pharmaceutical manufacturing company did not allow USB devices to be plugged into its computers for security reasons.

To meet this client request, PV adapted the process by uploading all the videos to a secure cloud storage service. They meticulously managed the uploads, ensuring that each video was properly transferred and accessible to the stakeholders.

Challenge #6: Scope Changes

Due to the robust equipment, PV was able to pivot quickly to meet the client's needs due to having additional execution equipment on hand. PV's ability to adapt quickly and plan for the unexpected allowed the team to keep the project on track while delivering high-quality results.

Project Summary

Through the successful completion of comprehensive smoke studies, PV helped the pharmaceutical manufacturing company close its CAPA and secure confidence in its compliance. The project's primary goal of ensuring operator safety was achieved by meticulously examining and documenting the containment capabilities of packaging rooms under specific conditions.

The detailed smoke studies provided the necessary data to justify the adjustment of the room pressurization alarm delay, addressing the auditor's concerns.

PV implemented a strategic approach to ensure all team members were in the right place while also managing costs and availability. For this particular project, PV sourced local team members to save the client money on travel expenses.

Overall, the project was completed within the client's schedule and under budget, demonstrating PV's commitment to excellence and the pharmaceutical manufacturing company's dedication to maintaining stringent safety and compliance standards.

Your Validation Partner for What's Next

Performance Validation (PV) is a global Commissioning, Qualification and Validation partner for pharmaceutical and medical device manufacturers, extending its expertise to include Building Commissioning for Building Owners in a broader scope of industries. Headquartered in Indianapolis, IN, we specialize in turning compressed timelines into compliant ones across a diverse array of environments, using innovative, adaptive approaches that balance production realities with strict regulatory requirements. With Building Commissioning, we leverage our deep understanding of regulatory standards to ensure facilities operate at peak performance, enhancing efficiency, safety, and environmental sustainability. Our dedicated team, consisting of more than 95% engineers, works closely with regulators, equipment suppliers, and construction teams to keep validation and commissioning services ahead of production curves, ensuring quality and operational excellence across all projects.