ENSURING EU ANNEX 1 COMPLIANCE WITH EXPERT ROOM RECOVERY TESTING FOR A PHARMACEUTICAL MANUFACTURER

AT A GLANCE

A large pharmaceutical manufacturer in Indianapolis, IN, partnered with Performance Validation (PV) to validate that its air handling systems in classified cleanroom airlocks effectively removed airborne particles, ensuring compliance with the updated EU Annex 1 requirements.

Services Provided

- Document Development
- Document Execution
- Equipment Expertise
- Room Recovery Testing

PERFORMING ROOM RECOVERY TESTING FOR AIR HANDLING SYSTEMS

Performance Validation (PV) was tasked with verifying that a pharmaceutical manufacturer's air handling systems servicing its Grade C and D airlocks operated effectively to reduce airborne particulate concentrations (particle size ≥ 0.5 µm) to an "at-rest" state within 20 minutes, as specified by EU Annex 1 guidelines.

To execute the room recovery testing, PV assembled a two-person team equipped with:

- Two Climate particle counters
- One Di-Ethyl-Hexyl-Sebacate (DEHS) aerosol generator
- Multiple Rosco and C Breeze glycol foggers
- Extension cords
- A cart for efficient transportation of equipment

PV began by identifying the airlocks requiring performance verification and setting up particle counters in the locations outlined in the test case diagram. To introduce airborne particulates, the team generated a controlled burst of fog or aerosol, typically lasting about five seconds, to achieve a measurable particle concentration. Following this step, all personnel exited the room to ensure the airlock doors remained securely closed and undisturbed for the duration of the test.

After a 20-minute recovery period, the team retrieved the particle counters and printed the recorded data for inclusion in the test case documentation. PV then analyzed the results against the established acceptance criteria, requiring a cleanup index (CICF) of at least 100. This metric was calculated by dividing the initial particle concentration (CI) by the final particle concentration (CF).
By successfully achieving the required cleanup index, PV validated that the air handling systems met the specified cleanliness standards within the defined recovery time, ensuring compliance with EU Annex 1 guidelines.

PERFORMANCE VALIDATION
Moving Quality Forward

SOLUTIONS-DRIVEN STRATEGIES FOR PROJECT SUCCESS

Performance Validation (PV) applied meticulous planning and innovative problem-solving to address challenges related to equipment limitations, environmental controls, and testing protocols, ensuring a seamless and compliant room recovery testing process.

EVALUATING AND IDENTIFYING OPTIMAL PARTICLE GENERATION EQUIPMENT

During the room recovery testing, PV encountered several equipment-related challenges and conducted a rigorous evaluation of multiple particle generation devices to identify the most effective solution for the client's cleanroom environment.

Initially, PV explored the use of the C Breeze handheld glycol fogger, which utilized propylene glycol. While this device offered simplicity and portability, it proved insufficient for the rigorous demands of room recovery testing.

The Rosco fogger, another option, demonstrated the capability to produce large volumes of fog quickly. However, its excessive output, reliance on proprietary fog fluid, and chemical incompatibility with Di-Ethyl-Hexyl-Sebacate (DEHS) during trials rendered it unsuitable for the project's requirements.

After a comprehensive evaluation, PV selected the DEHS aerosol generator as the optimal solution. This device consistently produced uniform particle concentrations and offered excellent cleanability, as DEHS evaporated rapidly within hours. Its performance and practicality ensured that the testing process aligned with both the technical requirements and regulatory standards.

By methodically addressing these equipment challenges, PV delivered a reliable and compliant solution that met the client's specific needs and supported the project's overall success.

PREVENTING TESTING DISRUPTIONS WITH CLEAR SIGNAGE ON AIRLOCK DOORS

Another critical challenge PV addressed was ensuring that airlock doors remained closed throughout room recovery testing. Even a momentary opening of a door could compromise the controlled environment by introducing a surge of airborne particles, jeopardizing the accuracy of the results.

To prevent such disruptions, PV implemented a proactive solution: posting clear and highly visible signs on all connecting doors. These signs effectively communicated the importance of keeping the doors closed, ensuring personnel awareness and adherence during testing. This simple yet impactful measure safeguarded the integrity of the test environment and contributed to the project's overall success.

ELIMINATING PARTICLE INTERFERENCE BY POWERING OFF ADJACENT EQUIPMENT

Managing equipment in adjacent rooms posed a unique challenge, as certain machinery inadvertently generated particles that interfered with testing results. In one instance, a test failed when a vial washer in a neighboring room emitted steam particles, even in its idle state, compromising the controlled conditions necessary for accurate measurements.

To resolve this issue, Performance Validation (PV) implemented a straightforward yet essential solution: ensuring all equipment in adjacent rooms was powered off prior to testing. This proactive measure eliminated unintended particle generation, preserved the integrity of the testing environment, and enabled precise and reliable outcomes for the client.

MEETING EU ANNEX 1 REQUIREMENTS WITH TECHNICAL PRECISION

Through a tailored testing strategy and meticulous execution, Performance Validation (PV) enabled the pharmaceutical manufacturer to demonstrate compliance with the stringent EU Annex 1 requirements for cleanroom recovery periods.

To minimize disruptions to daily operations, PV conducted room recovery testing within the client's designated execution windows. With typical windows allowing two days to test up to 12 rooms, PV efficiently tested 5 to 6 rooms per day, completing each test in approximately one hour.

PV's flexibility, technical expertise, and unwavering commitment to excellence ensured the project was delivered on time and within budget, meeting all regulatory requirements and operational objectives.

YOUR VALIDATION PARTNER FOR WHAT'S NEXT

Performance Validation (PV) is a global validation partner for pharmaceutical and medical device manufacturers. Headquartered in Indianapolis, IN, we specialize in turning compressed timelines into compliant ones using innovative, adaptive approaches that balance production realities with strict regulatory requirements. Our best-in-class, cGMP-compliant services cover diverse needs from fully managed CQV to on-demand temperature mapping, smoke studies, software assurance, and more. With a dedicated team consisting of more than 95% engineers, we work closely with regulators and equipment suppliers to keep validation ahead of production curves and keep quality moving forward.