EFFICIENT ENVIRONMENTAL MAPPING FOR A MAJOR PHARMACEUTICAL MANUFACTURER'S FACILITY EXPANSION

AT A GLANCE

One of the largest pharmaceutical manufacturers in the Midwest partnered with Performance Validation (PV) to perform environmental mapping in its brand-new facility in Research Triangle Park, North Carolina.

The pharmaceutical manufacturer expanded its operations by building a new campus to increase production capacity. One of its buildings included a quality control laboratory for testing and releasing pharmaceutical product samples.

As one of the pharmaceutical manufacturer's major partners, PV performed environmental mapping for the quality control laboratory building. With over a decade of experience working with the pharmaceutical manufacturer and its processes and decades of environmental mapping expertise, the PV team successfully overcame challenges during the project.

Comprehensive Environmental Mapping Services

The PV team's primary role throughout the engagement involved environmental mapping in equipment and laboratory rooms. PV developed the risk assessments for all the equipment used to store pharmaceutical samples, which included:

- Two (2) freezers
- Two (2) ultra-low freezers
- Twenty-four (24) refrigerators
- Six (6) benchtop incubators
- Eight (8) temperature-cycling incubators
- Twelve (12) floor-mounted standard incubators
- Five (5) reach-in stability chambers
- Two (2) walk-in stability chambers
- One (1) automated sample management system

The PV team also created risk assessments and mapping frequencies. The risk assessment considered various factors, such as equipment location and potential risk to the process.

Additionally, PV produced a mapping strategy that considered what was being stored or processed within the equipment and the operations in different facility rooms. PV developed testing procedures based on these strategies that aligned with the risk assessments and mapping needs. As the facility came online, PV prioritized the mappings based on the most critical needs.

This preparation was crucial because it allowed PV to fine-tune the testing process and ensure the equipment would perform as expected. PV's attention to detail and proactive approach meant the process would be smooth, clean, and free of surprises when the pharmaceutical manufacturer conducted the final factory testing. Their work behind the scenes minimized the risk of last-minute changes or delays, contributing to a successful and efficient factory testing experience.

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Services Provided

- Risk assessments
- Mapping strategies
- Remapping frequency
- Humidity mapping
- Resource management

Providing Innovative Solutions for Unique Challenges

During the project, several challenges arose that threatened to delay the timeline and impact the project's overall success. PV used its experience and ingenuity to create actionable solutions to mitigate the risks.

Accelerating Lab Readiness with Additional Resources and Expertise

As the pharmaceutical manufacturer's equipment arrived on-site, the lab needed to ensure various resources were ready for use as different portions of the facility came online. Some testing had to be prioritized and completed faster to align with the overall strategy for bringing the facility online in stages. PV successfully met each milestone.

Due to upstream construction delays, the testing window was reduced. To maintain the client's schedule to meet market demands, PV brought in extra environmental mapping equipment and more team members to help meet the original timetable with a reduced testing period.

Pinpointing Equipment Control Issues for Fast Resolutions

During equipment mapping, PV found some devices operating outside the desired ranges. Based on the mapping results, the PV team provided insight into the necessary adjustments to bring the system to the client's specifications. PV's years of experience with temperature mapping helped to identify the root causes of issues from the data analysis. This provided the ability to swiftly implement the right corrective actions so the systems could be brought online on or before schedule.

For example, PV pointed out malfunctioning components or suggested adjustments to specific system control parameters to bring the equipment within the required operating range. Based on PV's recommendations, the pharmaceutical manufacturer either made the adjustments themselves or engaged third-party vendors to repair/tune the equipment properly. PV was able to pinpoint the likely cause of the issue, helping to resolve the problem effectively.

Identifying Unsuitable Equipment & Recommending Alternatives

The pharmaceutical manufacturer purchased new equipment for its quality control laboratory. Before testing, PV evaluated the equipment to explore its capabilities and determine if it met the client's process needs. PV found that the provided equipment was unsuitable for the intended use because the equipment did not meet the required control ranges of the pharmaceutical manufacturer's testing procedures.

The PV team explained the situation to the client and offered equipment recommendations based on experience with similar processes. In the end, the pharmaceutical manufacturer invested in equipment that met its needs, which helped prevent future operational challenges.

Offering Corrective Actions for the Facility's Construction

PV collaborated with the client to identify issues with the facility's construction prior to execution. For example, the monitoring system was installed in a manner that would have led to inaccurate measurements during normal operation. PV worked with the client to find the best corrective action to meet the client's needs and mitigate the issues.

Another example of corrective action occurred during execution. PV suggested adding window tinting to improve environmental control. Although the client had already built the facility, the PV team was able to suggest adjustments early enough in the process to help find solutions.

Standardized Testing for New Automated Sample Management System

The pharmaceutical manufacturer purchased a new, automated sample management system that it had never used in a GMP state. Therefore, no testing standards were in place.

Drawing on their experience with similar technologies, the PV team consulted with the client to develop a global standard for testing this equipment. As a result, PV helped ensure consistent, reliable testing procedures aligned with industry best practices.

Precise Environmental Mapping Meets Milestones and Provides Ongoing Client Support

PV successfully performed environmental mapping in 18 laboratory spaces and over 50 pieces of equipment ranging from walk-in units to benchtop units, completing the project on time and within budget.

The pharmaceutical manufacturer had several milestones to bring different parts of the facility online as part of the larger campus activation. PV successfully met these milestones, ensuring the equipment was online within the required timeframes.

As the client continues to expand its operations, it has hired PV to help with other environmental mapping projects and provide ongoing monitoring support. This included mapping several new API production, parenteral manufacturing, packaging, and logistics facilities and all associated equipment. The client also asked PV to help improve and develop new best practices.

PV is also the go-to temperature mapping and environmental control subject matter expert for answering any questions on the pharmaceutical manufacturer's projects. This includes offering design consulting for the other facilities being constructed. PV also serves as a member of the client's temperature mapping forum, driving process improvements across its network.

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.

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