

# COMPLIANT QUALIFICATION & TEMPERATURE MAPPING FOR A LOGISTICS COMPANY'S GMP WAREHOUSE FACILITIES

## AT A GLANCE

A third-party logistics (3PL) company partnered with Performance Validation (PV) to qualify and conduct temperature mapping for its GMP warehouse facilities in Indianapolis, IN and Phoenix, AZ.

To support the expansion of its pharmaceutical and life sciences operations, the company needed to design, construct, and qualify GMP-compliant warehouse spaces capable of safely storing and distributing client materials. With clients already relying on the anticipated functionality of these facilities, the project demanded a highly efficient and timely commissioning process. Leveraging its proven expertise in GMP compliance and validation, PV was selected to lead the qualification, temperature mapping, and overall validation efforts.

## Services Provided

- Initial Facility Commissioning
- Initial, Seasonal, and Repeat Temperature Mapping
- Qualification Commissioning
- Master Plan Development
- Project Management
- Commissioning Summary Report Development
- eQMS and Warehouse Management System Validation

## ENSURING REGULATORY COMPLIANCE WITH DEDICATED SERVICES



Over a three-year period, PV provided comprehensive commissioning, qualification, temperature mapping, and electronic quality management system (eQMS) validation services to ensure that all three GMP warehouse facilities in North Indianapolis, IN, South Indianapolis, IN and Phoenix, AZ met stringent regulatory and operational standards within the required timelines.

## ON-SITE COMMISSIONING, QUALIFICATION & TEMPERATURE MAPPING SUPPORT



PV delivered on-site expertise at the logistics company's Indianapolis, IN locations, assisting with commissioning, qualification, and temperature mapping for temperature-controlled systems.

Most of the facility's storage spaces were designated for controlled room temperature (CRT) storage, maintaining a range of 20 to 25°C for pharmaceutical materials and products. Additionally, the facilities were equipped with specialized storage areas, including refrigerated units maintaining 2 to 8°C, walk-in freezers capable of reaching -25°C, and a dedicated room housing ultra-low freezers for temperatures as low as -80°C.

PV collaborated with the facilities construction team to develop commissioning and qualification protocols, leveraging its specialized expertise in temperature mapping. This critical process was conducted in two distinct phases: an initial mapping of the GMP storage areas in an empty state and a subsequent mapping conducted after the spaces were loaded with materials. Subsequent mappings were done during opposite seasonal extremes to capture both heating and cooling operational conditions within the warehouses.

The scope also included the qualification of temperature-controlled trailers designed to transport GMP materials. These trailers required precise validation to ensure consistent temperature control during transit. The logistics company provided the qualification protocols, and PV supported the process by managing the temperature mapping activities.

## REMOTE TEMPERATURE MAPPING FOR EFFICIENT COMPLIANCE & OPERATIONAL SCALABILITY



When seasonal remapping was required at the Phoenix, AZ facility—originally commissioned and temperature-mapped by another vendor—the logistics company sought PV’s specialized expertise based on the successes of the Indianapolis facilities. Following the remapping, the facility underwent significant expansion, doubling in size and requiring additional commissioning and temperature mapping to accommodate the increased capacity.

Without local resources near the Phoenix site, PV delivered remote support for both the seasonal remapping and the facility expansion. Drawing from their extensive temperature mapping experience, PV developed tailored protocols based on proven methodologies from previous projects. Temperature mapping equipment was shipped to the logistics company, where on-site personnel, guided by PV’s detailed instructions, installed and removed the sensors for the mapping studies. The equipment was then returned to PV for comprehensive data analysis to verify compliance and performance.

For the expanded facility, PV continued to provide remote oversight, assisting the logistics company’s document manager in protocol execution and ensuring accurate temperature mapping through a structured, step-by-step process. By leveraging technical expertise and an efficient remote strategy, PV ensured the Phoenix facility met stringent regulatory requirements while supporting the company’s operational growth.

## REMOTE EQMS VALIDATION



To support the secure storage and distribution of GMP materials, PV validated the logistics company’s QT9™ electronic quality management system (eQMS). PV developed a robust validation plan to ensure compliance with 21 CFR Part 11 and FDA CGMP standards, addressing critical regulatory requirements, data integrity, and operational needs.

Collaborating closely with the client, PV ensured the eQMS met stringent compliance standards while delivering tailored standard operating procedures (SOPs) to support future system updates and audits. This proactive approach positioned the client for ongoing regulatory success and operational efficiency.

## OVERCOMING CHALLENGES WITH COLLABORATION, FLEXIBILITY, & EXPERTISE



Throughout the project, Performance Validation (PV) overcame various challenges by fostering strong collaboration with stakeholders and maintaining clear, consistent communication. PV’s technical expertise was instrumental in addressing system inefficiencies, while their adaptability allowed the team to effectively respond to shifting timelines and evolving project requirements.

By prioritizing quality and precision, PV ensured that all validation requirements were met, enabling the logistics company to achieve its operational and regulatory goals within the project’s scope.

## ENSURING QUALITY DOCUMENTATION WITH CONSTRUCTION CONTRACTOR



PV worked closely with the construction contractor for all three facilities to ensure the accurate and timely completion of critical documentation. PV meticulously documented all start-up activities, establishing a solid foundation for operational success. The collaborative approach proved particularly effective at the first site, where the process was refined and subsequently replicated across the remaining locations.

For the rooftop air handling units, a separate vendor was responsible for completing the start-up checklists. When initial submissions did not meet PV's stringent quality standards, PV proactively engaged with both the contractor and vendor to address the deficiencies. By providing detailed guidance, PV ensured the documentation was revised to align with the project's rigorous requirements. This collaborative effort upheld the project's quality benchmarks and ensured operational readiness across all facilities.

## PROVIDING TECHNICAL EXPERTISE TO RESOLVE CONTROL ISSUES WITH ROOFTOP AIR HANDLING UNITS



A key complication arose from the contractor's inventory of air handling units, which had been stored for an extended period. While this allowed for expedited installation, prolonged storage led to functionality issues and deviations from facility specifications. Troubleshooting these problems required close coordination between the contractor and equipment vendors to identify and resolve the root causes.

Given the scale of the project, with multiple large facilities and numerous air handling units, maintaining, and upgrading equipment was a significant undertaking. PV provided critical support by offering clear, actionable guidance, prioritizing urgent repairs and replacements while identifying tasks that could be deferred to later phases. By balancing immediate needs with phased testing, PV helped maintain project momentum, ensuring compliance and optimal system performance without unnecessary delays.

PV's flexibility, technical expertise, and collaborative approach were essential in overcoming these challenges, driving the project to a successful outcome.

## MAINTAINING MOMENTUM THROUGH FLEXIBLE SCHEDULING SOLUTIONS



The Phoenix facility faced scheduling challenges that required adaptability and close coordination among all stakeholders. While the logistics company managed the fieldwork, delays in their progress impacted the overall timeline and PV's planned involvement during the final stages of the project.

As the final step of the process, PV maintained a state of readiness, ensuring that equipment and resources were prepared to deploy as soon as the logistics company was ready to proceed. This proactive approach allowed PV to adapt to shifting schedules while maintaining efficiency and preserving project outcomes.

By demonstrating flexibility and fostering seamless collaboration, PV successfully mitigated the impact of scheduling delays. The team ensured that validation and temperature mapping efforts were completed on time and upheld the highest quality standards, enabling the project to achieve its objectives without compromise.

## ALLEVIATING PROJECT CONCERNS WITH THE NEW QUALITY DIRECTOR



Midway through the engagement, the logistics company appointed a new quality director, bringing fresh perspectives and heightened expectations to the validation process. With a strong GMP background, the director introduced specific requirements and initially raised questions about PV's approach to achieving project objectives.

Performance Validation (PV) proactively addressed these concerns through open communication, close collaboration, and technical expertise. By engaging directly with the director and contractor, PV developed tailored solutions that adhered to GMP standards while ensuring project timelines remained on track. This approach not only resolved the director's concerns but also highlighted the effectiveness and reliability of PV's methodology.

The successful resolution earned positive feedback from the GMP client utilizing the validated space and established the new director's confidence in PV's capabilities. This trust became a cornerstone of the partnership, leading to PV's expanded role in future projects across the logistics company's other sites and further strengthening their collaborative relationship.

## TIMELY & COST-EFFECTIVE VALIDATION & TEMPERATURE MAPPING



Despite external delays beyond PV's control, Performance Validation (PV) delivered its portion of the project on time and within budget, ensuring the validation process was completed ahead of the facility's operational timeline. PV carefully coordinated testing and documentation to align with the project's specific requirements, guaranteeing both compliance and readiness.

For the new Indianapolis facilities, PV proactively recommended and executed a preliminary short-term temperature mapping of select spaces. This scaled down, 24–48-hour approach validated the environment in advance of the full-scale mapping, providing a strategic foundation for the official temperature mapping process. This proactive step ensured all requirements would be met efficiently and effectively.

The full temperature mapping process was successfully completed, meeting all critical criteria for CRT storage, coolers, and other equipment. The comprehensive dataset generated through this process confirmed system performance and validated the facility's readiness for operations, reinforcing PV's commitment to quality and precision.

## 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.