

AT A GLANCE

In a landmark project within North Carolina's Research Triangle Park, Performance Validation (PV) executed a comprehensive temperature mapping study for a leading pharmaceutical manufacturer's state-of-the-art Automated Storage Retrieval System (ASRS) facility. Spanning two crucial storage areas—Controlled Cold Temperature (CCT) with >9000 pallet positions and Control Room Temperature (CRT) with >8000 pallet positions—the project utilized 371 Vaisala Data Loggers to ensure precise temperature control critical for drug product storage. The initiative encompassed extensive mapping under various conditions, including empty, simulated full, and open door scenarios, to validate compliance with the United States Pharmacopeia (USP). Leveraging advanced data analysis and risk assessment methodologies, the project addressed unique ASRS challenges, ensuring optimal operational efficiency and product and patient safety through innovative temperature management solutions.

Services Provided

- Comprehensive Temperature Mapping
- Advanced Data Analysis
- Risk Assessment Methodologies
- Strategic Logger Deployment
- Operational Resilience Strategies
- Real-World Condition Simulation
- Engineering Studies
- Protocol Development and Execution
- User Requirements and Temperature **Control Specifications**
- Summary Reporting

NAVIGATING COMPLEXITY: MASTERING DATA LOGGER PLACEMENT IN HIGH-DENSITY STORAGE >



The project's initial hurdle was the precision required in positioning data loggers within the high-density, automated storage configuration. This task necessitated an in-depth understanding of the ASRS architecture and meticulous planning to ensure comprehensive temperature monitoring coverage.

Performance Validation tackled this challenge head-on by conducting a detailed analysis of the facility's blueprints and leveraging industry best practices. This enabled the strategic deployment of 371 data loggers, ensuring every critical area within both the CCT and CRT spaces was accurately monitored, thus guaranteeing the integrity of the temperature mapping data.

OVERCOMING ADVERSITY: RESPONDING TO UNFORESEEN OPERATIONAL CHALLENGES



Unexpected operational issues, including equipment failures and power outages, threatened the integrity of the temperature mapping process. These variables introduced significant complexity, requiring flexible and adaptive strategies to maintain project continuity and data accuracy.

The team's response was twofold. Firstly, they swiftly adapted to these challenges by modifying the test protocol to accommodate for the interruptions, ensuring data collected reflected normal operational conditions. Secondly, the occurrence of equipment failure prompted an in-depth engineering study, reassessing the operational requirements of equipment systems to meet storage space condition requirements leading to strategic operational modifications.

ENHANCING OPERATIONAL RESILIENCE: SIMULATING **REAL-WORLD CONDITIONS**

Accurately predicting the temperature dynamics within a fully stocked dense-storage warehouse posed a unique challenge, necessitating the simulation of real-world conditions to validate the ASRS's operational resilience.

Performance Validation strategically placed pallets to restrict air flow throughout the space alongside load pallets equipped with loggers, creating a simulated worst-case full-stock scenario. This approach provided invaluable insights into the system's performance under various operational conditions.

Additionally, Performance Validation provided testing within different operational worst-case conditions, including door openings, thereby ensuring the facility's readiness for real-world demands.







Phase 1

Risk Assessment



Protocol Development



Protocol Execution

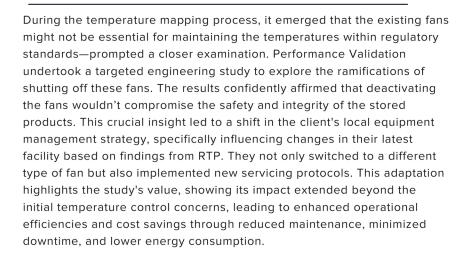


Data Analysis

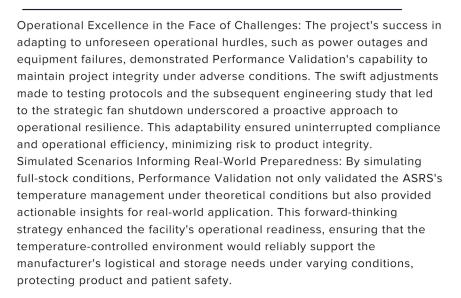


Project Summary Report

ENGINEERING INSIGHTS: BEYOND TEMPERATURE MAPPING



ACHIEVING OPERATIONAL EXCELLENCE: THE END-TO-END BENEFIT OF PRECISION TEMPERATURE MAPPING



CONCLUSION: SETTING NEW STANDARDS IN TEMPERATURE-CONTROLLED STORAGE

Performance Validation's temperature mapping project in Research Triangle Park exemplifies innovative solutions in ensuring regulatory compliance and product safety for automated storage systems within the biopharmaceutical industry. By skillfully navigating complex storage configurations, responding with agility to operational challenges, and delivering strategic insights that extend beyond immediate project goals, this initiative not only met pharmacopeia standards but also advanced operational efficiency and sustainability for the client. The project stands as a benchmark in the industry, showcasing the importance of precision, adaptability, and innovative problem-solving in maintaining the integrity of temperature-sensitive pharmaceutical products.

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.

