AT A GLANCE

A global pharmaceutical manufacturer sought to replace their digital and paper-based temperature monitoring systems with a single, secure, digital, continuous monitoring solution across its U.S. manufacturing site. The multi-year project covered every lab, freezer, cooler, warehouse, and stability chamber—requiring phased validation, coordination across multiple departments, and adaptation to shifting priorities during the COVID-19 pandemic. Partnering with Performance Validation (PV), the client achieved a 40-year leap in monitoring technology, improving compliance, efficiency, and data integrity.

SERVICES PROVIDED

- Project Management
- Validation Protocol Development & Execution (IQ/OQ)
- System Configuration & Data Integrity Testing
- Equipment Qualification in Phased Rollouts
- Training Support for SOP Development

OUTDATED PROCESSES COULD NOT KEEP UP WITH COMPLIANCE DEMANDS ⌄

A large percentage of the client's existing temperature monitoring for environmental chambers and lab coolers/freezers relied on paper chart recorders, with no automated alarms and limited visibility outside of the room they were housed in. This made audits labor-intensive and delayed detection of temperature excursions, which could jeopardize product quality.

The client did have a homebrew digital monitoring system for the warehouse and for certain freezers, but it was not scalable and was on an outdated, hardwired system. New requirements under 21 CFR Part 11, along with the inefficiency of these legacy systems, drove the need for a secure, compliant digital solution that could consolidate everything under one umbrella.

A DIGITAL, SECURE, AND SCALABLE MONITORING SYSTEM ⌄

PV validated a sitewide monitoring solution built on Vaisala ViewLinc technology. The system integrated wireless and wired data loggers, each capable of storing 30 days of minute-by-minute readings. Data was transmitted every five minutes to a secure site LAN, physically isolated from the internet to protect against cybersecurity threats.

The system offered:
- Role-based access so users only received alarms for the units they managed.
- Custom reporting for rapid retrieval of data during audits.
- Alarm optimization through programmed delay settings to reduce nuisance alerts without sacrificing accuracy.

In high-density freezer areas, PV validated wired connections to avoid wireless signal interference, ensuring uninterrupted monitoring in critical storage environments while still incorporating them into the same ViewLinc server.

PHASED VALIDATION TO COVER EVERY TEMPERATURE-CONTROLLED ASSET ⌄

PV's role encompassed the development and execution of all IQ/OQ protocols for the system and connected units. Validation was completed in phases, beginning with the system configuration and data integrity functions, then expanding into specific equipment groups, including:

- All laboratory environments
- COVID-related ultra-low (-80°C) vaccine freezers
- Stability chambers, thaw chambers, BQ lab units, and warehouse systems

PV also provided training support for recalibration processes, enabling the client to develop SOPs that support long-term system maintenance. Most work was performed on site, with remote documents and change control support during COVID restrictions.

ADAPTING QUICKLY TO EXPANDED SCOPE AND NEW PRIORITIES ⌄

Over the project's four-year timeline, PV adapted to evolving needs and circumstances:
- Stakeholder changes required onboarding new contacts to maintain alignment and continuity.
- Pandemic-driven scope expansion added 100–200 ultra-low temperature freezers for vaccine storage, increasing project value by nearly $200,000 and reprioritizing timelines.
- Concurrent changes to equipment configurations and mapping locations during qualification required close coordination to avoid delays and maintain accurate documentation.

DELIVERING A 40-YEAR LEAP IN MONITORING CAPABILITY ⌄

By project completion, the client had transitioned from paper chart recorders to a secure, compliant, and fully validated digital monitoring system. The upgrade delivered:
- Full compliance with 21 CFR Part 11 requirements.
- Reduced audit preparation from days to minutes.
- Reliable, targeted alarms and automated reporting.
- Scalable infrastructure supporting future facility and equipment growth.

EQUIPMENT USED

- Vaisala ViewLinc Continuous Monitoring System
- Vaisala Wireless and Wired Data Loggers
- AP10 Access Points
- Aluminum Heat Sinks for Temperature Stability

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