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Can AI Prevent the Next GMP Cold Storage Failure?

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As temperature-sensitive biologics, vaccines and cell and gene therapies become increasingly valuable and complex, traditional compliance monitoring alone may no longer be enough to protect critical products. Refrigeration systems can remain within specification even as compressors, seals, valves and other components quietly deteriorate



In conversation with **BioSpectrum Asia**, **Laurie Masiello and John Masiello, Co-Founders of Predictive Monitor**, explore how AI and predictive monitoring are changing GMP refrigeration and cold storage management. They discuss the limitations of conventional temperature monitoring, the growing importance of equipment-health intelligence, the skills gap in facilities management, and why the next generation of pharmaceutical manufacturing will increasingly shift from detecting excursions to forecasting failures before they occur.

Question 1. Predictive maintenance has become a major focus across regulated manufacturing. What are the biggest misconceptions biopharma companies still have about monitoring GMP refrigeration and cold storage systems?

- **"More data points automatically mean better predictions."**
  Companies imagine the volume of data from more sensors creates a predictive maintenance program. But that is only data. Predictive analysis uses that data against known failure signatures such as idle periods, environmental conditions, and other routine activities to determine why equipment is behaving a certain way. Raw temperature logs alone don't reveal mechanical degradation. Without strategically acquired data, you have cGMP compliance monitoring, not fGMP predictive maintenance.
- **Confusing continuous temperature monitoring (a validation/compliance requirement) with predictive maintenance (an engineering discipline).**
  This is probably the most common misconception. A validated monitoring system that alarms at excursion thresholds is designed to protect product data integrity requirements and satisfy 21 CFR Part 11 and EU Annex 11. Alarming when a unit has *already* drifted out of range doesn't catch the mechanical precursors — a slowly failing compressor, or a

gasket losing seal integrity. Continuous monitoring doesn't evaluate equipment health.

- **Assuming redundancy eliminates the need for predictive maintenance.**
  Many cold storage environments have backup compressors, backup power, and backup units. Some teams believe that redundant backup systems eliminate the need for predictive maintenance, confusing the two distinctly different processes as synonymous. In practice, redundant systems can mask a slowly degrading primary unit because the backup will engage, never revealing the failing equipment health of the primary unit. Predictive maintenance alerts you the primary unit needs service before relying on the backup system.

Question 2: As biologics, vaccines, and cell and gene therapies continue to expand, how should manufacturers rethink their approach to protecting temperature-sensitive products beyond traditional compliance and validation?

Traditional validation requires you to demonstrate, retrospectively, that the product stayed within spec. That's kind of a backward-looking, pass/fail framework. Cell and gene therapy (CGT) products in particular often have no backup batch, and a single patient's cells can represent the entire "lot." Losing one freezer isn't a deviation you write a CAPA for; it can be a therapy that never reaches a patient. That reality demands manufacturers understand failure mechanisms (e.g., compressor wear curves, defrost cycle drift, door-seal degradation, power transfer switch reliability) well enough to intervene before an excursion, not just document one after the fact.

A conventional biologic with continuous manufacturing and multiple lots has redundancy built into the process itself — if one lot is lost, another can be made. Autologous cell therapy does not have that redundancy. The patient's starting material may not be recoverable at all. This argues for a tiered cold-chain risk model where the *criticality of an individual unit's loss* drives how much redundancy, monitoring granularity, and predictive maintenance investment you apply. Many companies still size their cold chain infrastructure using biologic-era assumptions that don't hold for CGT.

Question 3: How is AI transforming refrigeration and critical infrastructure monitoring, and what measurable benefits have pharmaceutical manufacturers achieved through predictive monitoring?

AI, and particularly machine learning models designed for time series data, has transformed refrigeration and critical infrastructure monitoring by making it possible to process enormous volumes of sensor data that would previously have been too complex or noisy to analyze effectively. Rather than simply detecting that something has changed, AI evaluates equipment within its full operational context, incorporating factors such as operating state, chamber access, idle periods, environmental conditions, and other routine activities to determine why equipment is behaving a certain way. This contextual understanding enables true condition based observations, allowing the system to distinguish normal operational variability from the early signs of mechanical degradation. By analyzing assets only under comparable operating conditions, AI reduces false alarms while detecting developing issues earlier, enabling proactive maintenance before performance or product quality is affected.

Beyond collecting raw data, AI models can combine multiple signals (temperature, humidity, current draw, door-open frequency, ambient conditions, vibration, etc.) to build a more accurate picture of equipment health than any single sensor could provide. A temperature reading alone might look normal while temperature and current draw together suggest a specific component is malfunctioning.

Instead of having HVAC-R engineers manually defining every failure signature, ML approaches can flag "this doesn't look like normal operation" even for failure modes not explicitly programmed. This matters because refrigeration failure modes are numerous and site-specific, varying with the age of equipment, local climate, and usage patterns.

Question 4: Many organizations are facing a shortage of experienced refrigeration and facilities professionals. How can digital monitoring and predictive technologies help bridge this growing skills gap?

Predictive monitoring is often seen as an efficiency plan, but for many companies, it's a workforce continuity strategy. Experienced refrigeration technicians bring many years of knowledge and experience, so they know "That hum means the compressor's about to go," or "This unit always drifts before a defrost cycle fails". When they retire or leave, they take that knowledge with them. Well-built predictive systems can automatically be taught to encode and learn that tacit knowledge, turning it into detectable patterns and alarm logic, and effectively institutionalizing expertise that would otherwise be lost. This doesn't replace the expert; it captures a version of their pattern-recognition that survives their departure.

Predictive technologies can also help flatten the learning curve for new technicians who don't have years of site-specific history with a particular unit. The trend data enables them to see, for example, that a unit's current draw has increased 15% over the past month, giving even a new person some context and insight that would take years of tenure to develop instinctively.

Question 5. From your experience, what are the most common operational risks that remain undetected until they result in costly downtime or product loss, and how can companies proactively address them?

Refrigeration systems can mask developing problems remarkably well. Because multiple components work together to maintain critical GMP conditions, the system can often compensate when one component begins to degrade. Temperatures remain within specification, but behind the scenes equipment may be working harder, consuming more energy, and accumulating additional wear.

Refrigerant leaks are one of the clearest examples. They can persist undetected while the system compensates, eventually resulting in costly refrigerant loss, environmental impact, and potentially an emergency failure. Similar patterns occur with valves, compressors, electrical components, and other mechanical systems. Problems that could have been addressed early are often discovered only after they have caused additional damage or become operationally critical.

Preventing that requires more than collecting data. It requires collecting the right data, understanding where to look, and having the analytical tools to turn that information into actionable insight. That is where predictive platforms like OverShield provide value: identifying subtle changes early, while there is still time to intervene proactively rather than react to an emergency.

Question 6: Looking ahead over the next five years, how do you see predictive monitoring evolving within pharmaceutical manufacturing, and what strategic investments should life sciences companies prioritize today?

From anomaly detection to failure forecasting

Most current systems flag deviations after they've started, such as a temperature excursion. The next generation will forecast equipment and process failures days or weeks earlier, using degradation patterns in thermal, pressure, power, and other process data, rather than waiting for threshold breaches. Life sciences companies should invest in predictive maintenance solutions that possess these capabilities.

Regulatory posture catching up.

The FDA's push on Quality 4.0 and continuous manufacturing means predictive monitoring will move from "nice operational efficiency" to something closer to a compliance expectation, particularly for cGMP facilities.

Convergence of process and equipment monitoring.

Right now, these processes tend to live in separate monitoring systems, with PAT (process analytical technology) tools watching product quality, and CMMS/reliability tools watching machine health. Companies will increasingly need to invest in unified models that can attribute a quality deviation to its root mechanical or environmental cause, because regulators are pushing toward real-time release testing, which requires that link to be airtight.