



Monitoring Critical Conditions for Quality and Compliance

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How do life science companies ensure fail-safe monitoring of their controlled environments to maintain uncompromised product quality? They rely on a Vaisala Veriteq Continuous Monitoring System that delivers gap-free records and ensures full regulatory compliance.

One such company, a US-based molecular diagnostics specialist, collaborates with pharmaceutical firms to research disease biomarkers and the links between cancer and the human autoimmune system. The samples and reagents used in the research often comprise the life's work of hundreds of scientists and the hope of thousands of patients awaiting new therapies and treatments.

To preserve these valuable assets, the company previously

relied on a monitoring system that used simple, generic data loggers and chart recorders to record temperature and humidity in all laboratories and storage equipment. The system worked, but entailed several checks each day, tying up resources. The system's measurement and recording methods were effectively passive and incapable of communicating excursions to personnel.

Not only did the old system necessitate an immense time investment, it also left valuable, often

irreplaceable samples vulnerable to temperature excursions caused by system failures such as power outage or a break-down in one of the freezer units. The company decided to switch to the Vaisala Veriteq Continuous Monitoring System, which provides a method of staying in close touch with every monitored area, 24/7.

No More Gaps in the Data

The situation described above is nothing exceptional, as more and more organizations find that old recorders and manual methods to track temperature and humidity data no longer correspond to their needs. It is becoming clear that the best way to ensure the high quality of products and processes in FDA & EMA-regulated storage, processing and manufacturing is to invest in automated continuous monitoring instrumentation and systems.

The Vaisala Veriteq Continuous Monitoring System is a monitoring and alarming solution that provides secure and high accuracy records for temperature, humidity and other critical parameters. The system collects data remotely from a network of measurement instruments, stores it in a secure location, and gives automated alarms according to customer-specified thresholds.

The biggest benefit of the system, however, is its ability to guarantee a continuous record of gap-free data. Data are recorded independently at the point of measurement, and then backed up with triple redundancy to safeguard it from power failures and network problems.

Continuous monitoring and fail-safe data recording combined guarantee that vulnerable products remain protected at all times and full compliance with all regulatory requirements is assured.

No More Manual Work, No More Expensive Installation Projects

The system can be easily customized to suit different applications and needs. It is scalable from a single monitoring point to thousands distributed across several facilities and multiple locations. Installation is also cost-effective as the system deploys without a re-wiring or cabling to existing Ethernet-wired, Power over Ethernet, and WiFi networks.

What's more, multiple sites can be monitored from one location through a browser-based interface from anywhere in the network. By simply logging into the network, personnel with user permissions can set the system up to display real-time data, create reports on demand and automate frequently run reports with scheduled delivery by email to relevant staff.

Flexible reporting capabilities keep monitored environments compliant with FDA, EMA, the Joint Commission, CAP, AABB and other regulatory and accreditation



requirements. Detailed and summary reports can include values, locations, duration, acknowledgements and corrective actions, for example. Furthermore, all interactions with the system are documented, providing a complete record for compliance with regulatory and accreditation requirements.

Forewarned is Forearmed

After switching to the Vaisala Veriteq Continuous Monitoring System, the molecular diagnostics company found that the system's most beneficial feature compared to manually downloadable alternatives is that it sends immediate notification when anything changes.

This applies not only to changes in conditions of the monitored environments, but also to problems in the monitoring system itself. If a recorder is accidentally disconnected or the connectivity goes down because of a server issue, the system alerts staff to respond immediately.

It also points out exactly where the problem is.

The alarming capabilities are easy to configure, customize and automate. Escalating multi-threshold alarms can be defined to trigger a notification at the first sign of a problem, sending alerts to specified personnel via cell phone, pager, desktop display, dial-out phone, or email.

The molecular diagnostics company monitors refrigerators, freezers, and server rooms to cover all pieces of equipment that are vital to protecting their samples, reagents and laboratory areas. Multiple temperature thresholds have been set up for each monitored area, according to the seriousness of the problem a malfunction can cause.

The benefits of the alarms became evident in a situation where the monitoring system signaled that one of the company's freezers was going above its alarm threshold. At first, there seemed to be no explanation for the temperature rise; the difference was very subtle and the



freezer was within range for most of the day.

However, after close examination of the measurement data, the middle of the freezer was identified as the location of the temperature change, and a blockage in the cooling system was found. The company is convinced that without the system alerting them of the subtle temperature change, the problem would not have been discovered until the freezer had failed completely.

Combined Offering of Two Industry Leaders

Vaisala acquired Veriteq Instruments, Inc. in March 2010. The goal of the merger was to combine the strengths of two industry leaders to create an offering and services to the benefit of customers operating in strictly regulated life science markets.

Before the acquisition, Vaisala had a foothold in the global pharmaceutical market, but was largely considered an instrument provider. There was a need to strengthen and expand offering targeted at the pharmaceutical and other life science industry customers in order to bring additional capabilities to Vaisala, and consequently, added value to customers.

Veriteq was the leading provider of continuous monitoring systems

Quality problems can be very damaging, and it only takes the tiniest mistake or malfunction for them to occur (see examples below). The good news is the risk of something going wrong can be significantly reduced with a continuous monitoring and alarming system that provides complete records for measured parameters and the necessary safeguards for early warning of potential quality hazards.

Effects of compromised quality



What can (and does) go wrong



and data logging solutions for the life science industry, with strong competence in understanding the customers' needs and the regulatory requirements of the market. However, its operation was largely focused on the North American market, while Vaisala's global presence and the greater resources of a larger company created new oppor-

tunities for developing new products and services.

For the customer, the meaning of the acquisition can be summed up in one simple concept: a total solution from one supplier. A solution that is easy to buy and install, and easy to validate and use – a fail-safe choice for protecting high-value assets in life science environments.