

VAISALA / SUCCESS STORY

LIFE SCIENCES

Continuous Monitoring in Pharmaceutical Warehouses: Drug Manufacturer Manages Critical Parameters, GMP Compliance & Costs

Established in 1939, **YaoPharma** develops, manufactures, and markets generic medicines. A subsidiary of Fosun Pharmaceutical Corporation (~500M USD annual sales), YaoPharma employs more than 1100 people and is located in Chongqing, China. With a portfolio of over 200 products, YaoPharma covers a wide range of therapeutic areas, including: hepatic and cardiovascular therapeutics, antidepressants, anti-cancer drugs, antibiotics, and nutraceuticals. Throughout its 70-year history, YaoPharma has been widely recognized for its superior product quality. In particular, the company has China's largest and most advanced production line for lyophilized powder for injection, with dosage forms ranging from large and small volume parenterals, capsules, tablets, granules, and sachets.

YaoPharma's manufacturing processes satisfy China's Good Manufacturing Practice (GMP) standards. Since 2008, Yaopharma has implemented an internationalization strategy led by their cGMP project team to meet international guidelines. Yaopharma has since received a GMP certificate issued by Health Canada. The company has also initiated an Abbreviated New Drug Application (ANDA) program to streamline applications for US generic drug approval and is expected to meet the US cGMP standards within the next three years.

To ensure that YaoPharma continues to improve its product quality and meet regulatory guidelines, the company must monitor and alarm the temperature and relative humidity of storage areas and warehouses. In the past, YaoPharma used data loggers to measure and record temperature and humidity. The logger history was then manually downloaded for review and archiving. However, because this process is time-consuming and inefficient, YaoPharma sought a better solution.



Challenge

- YaoPharma must maintain the temperature and humidity of warehouse areas to specified levels.
- They require an enterprise-wide solution that can enable multiple users at different locations to manage their respective monitored areas remotely. Users must also have the ability to receive and respond to alarm notifications and run reports on demand.
- Some data loggers must be placed in hard-to-reach locations where it is not feasible to wire power and Ethernet connection. Ideally, data loggers could connect to the network via wireless or hard-wired Ethernet connectivity, or a combination of both.

Solution

- The viewLinc software, as part of Vaisala's Continuous Monitoring System, provides secure, permission-based access from any PC on YaoPharma's existing network.
- Flexible, user-selectable notification options allow alarms to be sent via e-mail or text to PCs and mobile phones.
- viewLinc provides complete data integrity with redundant recording. Data logger histories are stored on the server data base, in the user's PC and each data logger's memory — at the point of measurement.
- viewLinc reporting is compliant with FDA 21 CFR Part 11, with audit trail and several graphing/reporting options.
- In accordance with regulatory guidance, the viewLinc system has full IQ/OQ validation protocols.

Benefit

- YaoPharma's system administrators can now assign permissions for viewing data, setting thresholds, and acknowledging alarms to personnel. Alarms can be scheduled by day, time, and person.
- Monitored points can be named based on location (i.e.: Warehouse Row 14A, Shelf level 2) making it easy to respond to alerts of out-of-tolerance conditions.
- Triple redundant recording provides total data protection: no single point of failure — including network or power outage — will result in lost data.
- Industry-best sensor stability is ensured with Vaisala's comprehensive and economical re-calibration program.



The Challenge:

According to the internal quality standards of YaoPharma, all documentation requirements of the SFDA and FDA must be met. In addition to improving the efficiency of monitoring and reporting data for the sake of regulatory compliance, a real-time monitoring function with 24/7 alarming and fully compliant reporting was needed to ensure the safety and efficacy of all stored drug products. YaoPharma sought a continuous monitoring system that would eliminate the manual steps in generating reports, send immediate notification if conditions were heading out of tolerances, and provide an easily accessible way to monitor real-time trends in critical areas.

Solution:

During the purchasing process for a new monitoring system, YaoPharma evaluated several suppliers. They eventually selected the Vaisala viewLinc system. Mr. Zhou Yang, YaoPharma Project Manager explains why:

“We selected the Vaisala Continuous Monitoring System because the viewLinc software interface is browser-based and could be easily integrated into our current network. In addition, we appreciated the service-focused spirit of Vaisala’s team, who customized the solution in accordance to our needs.”

A Reliable Solution Enterprise-wide:

YaoPharma installed the viewLinc monitoring system in their warehouse to evaluate its performance before standardizing the system company-wide. “The system worked great,” said Mr. Yang. “So, we expanded the monitoring to our multi-layered warehouse, the cooling warehouse, our cold room and a special drug warehouse. We currently have a total of twenty-two data loggers with temperature and humidity sensors.” With the viewLinc Continuous Monitoring System installed in the company’s storage areas, managers at each YaoPharma site can view critical areas in real time, as well as receive alarm notification via PC, phone and pager. Alarm messages can be sent to personnel based upon their areas of responsibility and ability to respond. For example, regulatory personnel receive communication alarms and distribution center personnel receive out-of-limit alarms. “The viewLinc system simplified and centralized our monitoring of temperature and humidity,” said Mr. Huang Xin, YaoPharma’s Deputy Manager of Technical Support. “The audit trail, Event Log and alarming all ensures compliance to GMP, which is of great importance to us. Meanwhile, the design of viewLinc software is perfectly suited to the operating environments of our storage and warehouse areas.”

“We selected the Vaisala viewLinc system because of its simplified scalability. Based on the standard Ethernet software, we could deploy the monitoring system on our current LAN; this reduced installation costs significantly...”

*Mr. Huang Xin
Deputy Manager of YaoPharma’s
Technical Support Department*

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