

Efficient and Compliant Environmental Monitoring Safeguards Drug Quality in an Award-Winning Pharmaceutical Manufacturing Firm

Shanghai Fudan-Zhangjiang Bio-Pharmaceutical Co., Ltd was founded in November 1996 in Shanghai Pudong High-Tech Business Park. From the outset the company operated under its vision statement: “The More We Explore, The Healthier We Are.” Shanghai Fudan-Zhangjiang Bio-Pharmaceutical Co., Ltd specializes in innovative research, development, and production of biotechnology. As an innovator in the bio-pharmaceutical arena, the company holds intellectual properties as one of its key resources. Through nearly 20 years of hard work, Shanghai Fudan-Zhangjiang Bio-Pharmaceutical Co., Ltd has developed cutting-edge products such as genetically engineered and photodynamic drugs, as well as nano-technology. This work has resulted in competitive advantages that will allow Shanghai Fudan-Zhangjiang



Challenge

- The standards of the Fudan-Zhangjiang Bio-Pharmaceutical Co., Ltd ensure that temperature and humidity are maintained within application specifications in all laboratories, incubators, cryogenic refrigerators and storage areas.
- By adopting an enterprise-level monitoring solution, multiple users were enabled to remotely manage their areas of responsibility, generate customized reports, and receive remote alarms in the method most appropriate for each user: phone, PC display, text, or email.
- Sensor-to-network connectivity is flexible and ranges from Ethernet, to Wi-Fi, as required by an application.

Solution

- The viewLinc Continuous Monitoring System provides secure access from designated PCs on the network.
- Alarm notification is user-configurable and flexible, with options including: email, PC display, text to phone, local audible/visual, and more...
- Environmental data is backed up and archived automatically.
- The audit trail ensures that all historical data and charts/reports conform to the requirements of FDA 21 CFR part 11 and Annex 11.
- viewLinc has an optional IQ/OQ (Installation/Operation Qualification) for comprehensive validation.

Benefits

- System administrators can assign rights for accessing data, setting threshold values and sending information to relevant users.
- Alarm notifications are sent only to relevant personnel and include: date, time, recipient information, zones, and acknowledgements.
- Detailed, user-customizable naming and description of monitoring points makes the software user friendly and easy to learn.
- Complete data protection: autonomous power and memory ensure that no single point of failure results in lost data.
- Vaisala's world-class sensors ensure accuracy for up to one year.
- Service plans are available and can include installation, validation, calibration, and extended warranties.



Bio-Pharmaceutical Co. to bring numerous new medicines to market in the coming years.

Leveraging its capabilities in bio-pharmaceutical development and manufacturing, Shanghai Fudan-Zhangjiang Bio-Pharmaceutical Co., Ltd leads national R&D projects. These projects include the “National Key Science and Technology Project Program” and the “National High-Tech Research and Development Program” as well as Special Science and Technology Projects of China’s National Major New Drug Development Program. Since 1998, the company has been continuously recognized as a leader of Shanghai’s growing biotech and high-tech sectors. In addition, in 1999 the company was approved for an “Enterprise Post-Doctoral Research Workstation” by the Ministry of Personnel.

The Situation:

To guarantee drug quality and patient safety, Shanghai Fudan-Zhangjiang Bio-Pharmaceutical Co., Ltd formulated its internal standards to meet or exceed the requirements of cGMP regulations, FDA 21 CFR Part11 and Annex 11. Before upgrading their environmental monitoring system, the company used simple data loggers to measure and record temperatures. Personnel would manually record data for review and archiving at least twice every day. With dozens of data records in each production site, the quality management staff was unable



to ensure that records were collected at the same time, and on the same data points. Concerned about their ability to continue to meet regulatory requirements as operations grew, Shanghai Fudan-Zhangjiang Bio-Pharmaceutical Co., Ltd sought a better solution for environmental monitoring.

The Solution:

The Vaisala Continuous Monitoring System comprises multi-functional data loggers and viewLinc monitoring software. Data loggers feature integrated sensors for measuring temperature and humidity, or use current or voltage inputs to record pressure difference, CO₂, level, particles, conductivity and other critical parameters. Some types of data loggers can also integrate a Boolean channel for a gate switch or alarm contacts.

Each data logger can connect directly to a computer through a USB port, and to existing networks via Ethernet, PoE or WiFi. Powered by lithium batteries with a life-span of approximately 10 years, each logger also contains autonomous internal memory for recording parameters at the point of measurement. With independent power supply and storage capacity, records are never lost or compromised by power or network interruptions.

The viewLinc monitoring software is a Windows® operating system that delivers 24/7 monitoring, multi-stage alarming, (local and remote), real-time trends and continuous, gap-free records.

“We chose the viewLinc Continuous Monitoring System because Vaisala’s data loggers have reliable accuracy across our industry. We first adopted Vaisala’s temperature and humidity monitoring products in 2012, and since then we have continued to upgrade our temperature and humidity monitoring with Vaisala’s systems. Each upgrade has seen an increase in our work efficiency.”

“We’ve found Vaisala’s validation technicians are well trained, easy to work with, and continually provide onsite and remote assistance. They’ve provided detailed and careful training to our staff and we are pleased to have them as partners in helping us achieve our goals in Quality Control and regulatory compliance.”

*“One major difference between viewLinc and other monitoring systems is **Vaisala’s reputation for reliability in industrial measurement.** The system’s data loggers are very stable and accurate. The data recording, monitoring capabilities and reporting features of the viewLinc system are powerful – we can have data from dozens of monitored locations easily summarized into a report for comparison and analysis. This is extremely convenient and time-saving.”*

“viewLinc’s alarm functions are especially helpful because we can customize alerts by type, area, personnel schedules and recipients.”

—Zhou Dong,
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Shanghai Fudan-Zhangjiang
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