FUJIFILM Toyama Chemical Co., Ltd. Builds its Future as a Global Healthcare Solution Provider with Data Center & Compliant Monitoring

"In the future, I think investigational drugs are also expected to require compliance with PIC/S and the FDA. Since the alert notification function can swiftly identify deviation, it also contributes to cGMP compliance. The automated monitoring system has also enabled us to greatly reduce the time that our researchers spend on device management."

*Mr. Hideaki Hori,
Manager at Small Molecular
Research Department
Research Division*

On October 1 2018, FUJIFILM Toyama Chemical Co., Ltd. (FFTC) made a new start in order to accelerate the development of diagnostic and therapeutic drugs.

FUJIFILM Toyama Chemical has a wide range of promising new drug candidates such as influenza treatments and Alzheimer's therapeutic agents. Many of the products Toyama Chemical develops are adopted by global companies. Looking to the future, FFTC will work with FUJIFILM, which develops new drugs, to become a comprehensive healthcare company that delivers products in disease prevention, diagnosis, and treatment.

In order to promote appropriate use of pharmaceuticals, FUJIFILM Toyama Chemical actively promotes company-wide alignment in quality assurance.

Since adopting Vaisala's viewLinc Continuous Monitoring System (CMS) at its Research Division in 2013, FFTC has gradually expanded the monitoring system to its Production Control and Quality Control departments. In this article, we look at the best practices of FFTC's company-wide quality system that uses the latest in cloud-based server technology to implement Vaisala's viewLinc Continuous Monitoring System.

Research Division

Although FUJIFILM Toyama Chemical Research Division is also in charge of areas not subject to Good Manufacturing Practices (GMP), the team decided to adopt the Vaisala viewLinc system throughout its controlled environments due to viewLinc's track record as a dependable solution for monitoring, alarming and reporting in global operations, as well as its ability to support current Good Manufacturing Practices (cGMP) and Food and Drug Administration (FDA) 21 CFR Part 11. In 2017, FFTC standardized on viewLinc for all monitoring of controlled environments. In part this decision was based on support having been terminated by other systems that had been used to monitor controlled environments.

Since the main investigative focus of FFTC's pharmacological research involves clinical bacterial strains, they collect strains from facilities such as hospitals and store the samples in freezers. Freezer failure, as well as other factors leading to the loss of samples, is one of the greatest risks faced.

FFTC's Research Division had previously used temperature data loggers from another company before adopting the Vaisala viewLinc system and data loggers. But the non-Vaisala data loggers often made it difficult to respond immediately to deviation alerts as their alerts were sent by phone. With viewLinc, alerts are automatically sent via e-mail if a threshold is exceeded or communication failure occurs within the system. This facilitates immediate corrective action, such as transferring bacterial strains to another freezer, resulting in a significantly reduced risk of losing samples.

Furthermore, viewLinc's alert notification functions contribute to and simplify cGMP compliance. The system's GxP-compliant reporting is also effective for audits from the perspective of investigational drug and drug substances management because it enables FFTC to quickly assess a temperature or humidity deviation. Additionally, the viewLinc system's battery-powered data loggers ensure that in the event of a power outage, no data is ever lost. This has the added benefit of allowing the quality team to conduct in-depth post-deviation analyses.

Before installing the viewLinc system, data was collected by a researcher every few hours. But there were problems with manually gathering data, one logger at a time; including lack of reception, depleted ink in chart recorders, and printing errors. Multiple servers had to be maintained for disparate monitoring equipment. Since FFTC has limited access area, having a system that provides reliable remote monitoring

enabled FFTC to greatly reduce the time spent by researchers in data compilation and device management. With the viewLinc system, data is now centrally managed at a FUJIFILM Group's data center in a remote location, which also manages backups, updates, and troubleshooting.

Production Control Department

One of the main reasons the FFTC team decided to adopt the Vaisala viewLinc CMS was Japan's joining of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) in 2014. At that time, FFTC had yet to establish company-wide standards and practices for temperature mapping/validation. While FFTC's team was researching compliance with international standards and audits, they attended a Vaisala webinar. The training covered GMP concepts and illustrated on-site practices for compliance. The team was convinced that adopting a Vaisala solution would be the most effective approach to adopting a cGMP-driven quality approach in mapping and monitoring. Since a company-wide approach was required, FFTC's Production Control team worked with the Quality Assurance Division and further requested the participation of all relevant departments.

Before adopting Vaisala's viewLinc system, management of different types of loggers and data in various formats was complicated and difficult. With the viewLinc system installed, FFTC's team can now monitor conditions in its seven warehouses on a single PC. Responsible employees are immediately notified when deviations are likely to occur. Prior to viewLinc's installation, presenting data for audits from all warehouses in varied formats necessitated painstaking work. But with viewLinc as a single solution, reports on warehouse environments

are easy to generate and effective for audits. Concise reports in a standard format can be submitted easily and the team is able to handle inspections with confidence.

Using Vaisala data loggers for warehouse mapping, the team identified the seasonal cold- and hot-spots. Although there are several locations where it is difficult to install sensors, the Vaisala data loggers have the additional benefits of easy placement and simple networking.

> "When receiving FDA inspections, I sometimes notice that the inspector may think about things differently to Japanese companies. This is why it is extremely valuable to not only update information about regulatory reforms in the United States and Europe, but also learn what local companies actually experience and how they handle things. I also believe that we might be able to draw our future roadmap knowing the latest mapping operations overseas. These are all things that I want to use the various types of expertise of Vaisala for."

Mr. Osamu Yoshida, Production Control Department Manager

> "I believe that the existence of a system or function that enables a company to provide a logical explanation when a deviation occurs will become increasingly important in the future. Vaisala's viewLinc system has enabled us to both establish a quality system and improve efficiency."

Ms. Yoko Sugiura of the Testing Group Quality Control Department

Quality Control Department

Since one of the main products handled by FFTC's Quality Control Department is sterile injection agents, the department has dozens of incubators performing microbial tests in various temperature conditions. These incubators require rigorous control and reliable monitoring to avoid temperature deviations.

The Quality Control Department at FFTC had been using various types of loggers for each incubator before adopting the Vaisala CMS, which made data management quite complex at that time. It was necessary to check the data for dozens of incubators several times daily. It was also necessary to extract the recorded data of loggers on a weekly basis as some of the data loggers lacked sufficient storage capacity. There were

often situations where consumables such as batteries and paper needed replacing. Both scenarios allowed the possibility of gaps in the data.

Because temperature records have a major impact on laboratory inspections, FFTC's Quality Control division investigated the adoption of devices that would comply with international standards for the global market. When the team adopted the Vaisala CMS in 2016, it was in large part due to the system's international reputation in terms of sensor accuracy, data integrity, and global support capabilities.

Adopting the viewLinc system has enabled the FFTC team to not only ensure the reliability of its environmental data, but also increase efficiency by eliminating the need for frequent device checks. With viewLinc in place, all reports are managed on a PC and automatically delivered to responsible personnel. This report automation significantly improved the entire workflow, resulting in a reduction of annual work by 300 hours. In the three years since installing viewLinc, FFTC has seen almost no deviation in the results of calibrating the measured logger values indicating that FFTC's

controlled environments are reporting accurate temperature and humidity measurements. In addition, FFTC employees are extremely satisfied with the prompt responses of Vaisala support.

Since all logger data is now centrally managed, it is easier for FUJIFILM Toyama Chemical Co., Ltd. to submit data and provide explanations during audits. In recent years, the FDA has increased its focus on data integrity. Because viewLinc records are maintained in an audit trail that prevents modification, FFTC can present concise reports simply by entering a description of an event. This also allows the team to respond swiftly and appropriately to any inspector queries. Although regulatory focus on data integrity is now more stringent, FFTC can easily check viewLinc's audit trail on a monthly basis to find when and where any excursions have occurred. Those regular reviews have now become critical facets of both inspection and audit processes. FUJIFILM Toyama Chemical Co., Ltd. has fully incorporated their viewLinc system into their established quality system, enabling them to handle audits with foresight and confidence.

Challenge

- **Historical Records for Inspection:** To ensure compliance it is necessary to prove that regulatory requirements are met, but it was complicated and time consuming to compile reports in various formats from several types of data loggers and chart recorders.

- **Risk of losing samples:** The Research division required a system that would prevent the risk of losing samples.

  Quality Control required reliable monitoring of incubation conditions for microbial tests to ensure the quality of sterile products.

- **Burden of data collection:** Collecting logger data from dozens of locations several times daily, along with weekly data extraction and frequent replacement of consumables, was labor intensive.

- **Complex device management:** There was a limit to the recorded data that could be contained in various loggers due to issues with reception, consumable management for paper charts, and the operation of multiple physical servers, etc.

viewLinc's Solution

- **Automatic Reporting:** The viewLinc system reports comply with the FDA's 21 CFR Part 11 for audit trails, access control, reporting, and more.

- **Alarm notification:** The viewLinc system allows users to set threshold values and various notification options to enable alarms to be sent to PCs and mobile phones via e-mail and text.

- **Remote monitoring:** All measurement points can be monitored from a single PC enabling users to understand location status and manage conditions in real-time.

- **Redundant data storage:** Each data logger's history is saved to the viewLinc server, users' PCs, and locally within the memory of the data loggers.

- **Secure access:** Monitoring can be done via secure access from remote sites based on authorized permission and secure access control in viewLinc.

Benefits

- **Regulatory Compliance:** viewLinc prevents data modifications or tampering, ensuring that reports are effective for audits. Quick, standardized reporting enables efficient compliance.

- **Safeguarded Products & Processes:** E-mail alerts enable users to quickly assess situations in their monitored locations and perform counter measures efficiently and precisely.

- **Efficient use of personnel:** Labor required for device management and data collection was greatly reduced. Over 300 hours of extraneous labor were eliminated.

- **Simplified maintenance and improved security:** Managing data on FUJIFILM group's cloud server means that data can be centrally controlled at a remote data center. This enables secure data backup and improved operational control.