

Real-time Environmental Monitoring for the Manufacturing of High-quality Pharmaceuticals

Senju Pharmaceutical Co., Ltd.

Location: Hyogo, Japan
Completion: January 2021
Industry: Pharmaceutical



Customer challenges

Real-time monitoring of manufacturing environment data, pharmaceutical regulatory compliance, and trend monitoring using data

The results obtained

Maintaining and improving product quality and manufacturing environment through data visualization, improving efficiency of facility maintenance and realizing predictive maintenance, and complying with pharmaceutical regulations.



Executive Summary

Senju Pharmaceutical Co., Ltd. is a pharmaceutical company that manufactures ethical drugs, over-the-counter (OTC) drugs, and veterinary drugs for the ophthalmology and otorhinolaryngology fields. Senju Pharmaceutical is best known for its Mytear series of eye drops, but is also known in the pharmaceutical industry for providing drugs to treat rare diseases. Through drug discovery and manufacturing, the company contributes to eye health around the world.

Pharmaceutical companies are required to comply with a variety of guidelines issued by the U.S. Food and Drug Administration (FDA) and other government agencies to ensure the production of safe and high-quality drugs. Companies around the world, including Senju Pharmaceutical, are committed to strict quality control throughout the production process, from raw materials to final products, and must monitor and record data on the manufacturing environment.

To help maintain product quality, Senju Pharmaceutical's Fukusaki Plant has introduced Yokogawa's OpreX Environmental Monitoring System (OpreX EMS) for the recording and monitoring of environmental data such as temperature, humidity, and cleanroom differential pressure as well as manufacturing equipment operating data.

The Challenges

Environmental monitoring to comply with guidelines

To follow Good Manufacturing Practice (GMP) and meet Quality Management System (QMS) and other standards, pharmaceutical manufacturers must fully and accurately record and manage environmental data such as temperature, humidity, differential pressure, and particulates in manufacturing facilities, testing rooms, warehouses, and the like. This data must be continuously monitored.

In addition, computer systems that record environmental data are required to have Data Integrity, electronic records, electronic signatures, logical security, audit trail, and other functions that comply with FDA 21 CFR Part 11 (Part 11).

To help ensure compliance with these standards, the Fukusaki Plant introduced Yokogawa's OpreX Environmental Monitoring System (EMS). In addition to securing compliance, Senju Pharmaceuticals wished to address the following issues at its plant:

Aim of installing the OpreX EMS

Senju Pharmaceutical already used Yokogawa OpreX Data Acquisition series paperless recorders to record environmental data from manufacturing facilities, clean rooms, and the like, and they were all Part 11-compliant. However, since data was only stored on the recorders, there were the following issues:

- To access the recorded data, people had to remove each recorder's SD card.
- With all of the data on an SD card, there was the risk that the data could be lost due to loss or failure of the card.
- Environmental data could not be monitored in real-time from the company's offices.
- It was not possible to perform comprehensive trend analyses or make other uses of data that had been collected over long periods of time.

Toyotaka Okabe, General Manager of the Production Department at the Fukusaki Plant, looks back on the background of the introduction of OpreX EMS:

"Compliance with various guidelines is important, but I also wanted to eliminate operations that were dependent on the limited number of skilled people at our manufacturing site. Ideally, everyone should be able to see the data and quickly take the right action if they notice anything unusual. In Japan, we face issues such as rising job mobility, the diversification of work styles, and the need to transfer the knowledge of retiring veteran personnel. Trend monitoring and predictive analysis using data are essential for stable and high-quality manufacturing."

Yokogawa's Solution

Implementation of OpreX EMS

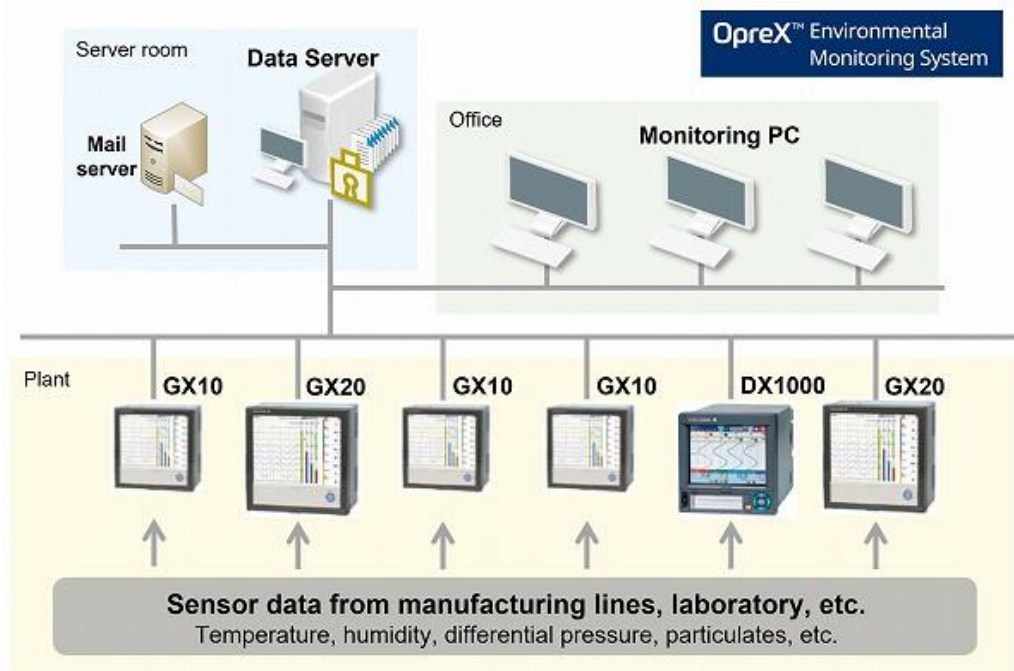
Kazuhiro Hasegawa, a project manager in the Production Department at the Fukusaki plant, drew up the request for proposal (RFP) for this project and held numerous meetings with Yokogawa to discuss it. He recalls how the system was introduced:

"Our Research and Development Department was the first to introduce the use of an environmental monitoring system at its laboratory. We had the need to visualize data and centralize its management on a company-wide basis, as well as to ensure compliance with GMP and other guidelines. As the Fukusaki Plant had long experience with Yokogawa's recorders, we could see the superiority of Yokogawa's OpreX EMS and decided to go with it. With this system, we can take immediate action when we receive an alert about a potential issue."

Yokogawa's personnel worked together with the members of the Fukusaki plant's project team to gather information on the existing recorder and network systems at this plant and draw up an optimal system configuration. Individual adjustments were made together with the companies that built the manufacturing and air conditioning equipment.

System overview

GX10 and other Yokogawa paperless recorders throughout the manufacturing facility collect temperature, humidity, and other data from wired sensors and store this data in internal memory and on SD cards. The Yokogawa paperless recorders meet the Part 11 and ALCOA+ Data Integrity requirements, and are highly secure. Via a network, data is transferred to the Data Server for long-term storage, and strict access control is implemented. This provides added protection against the loss of data.



OpreX EMS system configuration conceptual diagram

Using the GA10 Data Logging Software installed on office client PCs, supervisors can view both real-time data and data stored on the Data Server. Recorder settings can also be configured from the office. If an anomaly is detected with the sensor data, an alert e-mail is sent to the supervisors via the mail server. Alerts are also sent to the Data Server and displayed on the Monitoring PCs.

Utilizing real-time data

Noriaki Kiyomoto, a Group Manager in the Production Control Utility Department, appreciates the fact that data is visualized in real time:

"From the perspective of utility management, data visualization enables trend monitoring and preventive maintenance. Based on the data, it is possible to determine whether the equipment needs an overhaul or the replacement of parts. This makes it easier to secure maintenance resources. In the past, we relied on experienced veterans to do trend monitoring, and this was time consuming and laborious. Following the introduction of the OpreX EMS, data can be monitored quickly and easily, in real time. Environmental data at the plant site is collected in one-minute intervals. Based on this data, we can identify when air conditioners and other equipment are in need of maintenance."

The use of environmental data to ensure product quality

Takafumi Komada is an Assistant Manager of the Production Control Utility Department, and has been an advocate for the use of the OpreX EMS at the Fukusaki Plant. He proudly states that the visualization of data contributes to product quality:

"Temperature and humidity in the manufacturing room vary due to seasonal and other factors. The values fluctuate easily due when, for example, it is raining or equipment is being washed. In order to maintain product quality, it is important to keep room temperature and humidity within a fixed range. Thanks to OpreX EMS, we can take immediate action before these values deviate. So we believe that we can deliver high-quality products to patients waiting for our medicines."

Further data utilization

At the Fukusaki Plant, the introduction of the OpreX EMS is considered just a starting point. They aim to improve operations through means such as the analysis of manufacturing environmental data, linking this with PLC process data to acquire knowledge about the relationship between the data and actual phenomena. The OpreX EMS is not just a data acquisition system; it is expected to be used in various other ways to, for example, improve production efficiency and prevent unexpected equipment failures.

Customer Interview

-- What are the benefits of the OpreX EMS?

"Being able to see data on the manufacturing environment in real time is highly valuable. If no one notices an issue that causes a problem such as a drop in the cleanliness level in a clean room, this can have a great impact on the production schedule. Investigation of the cause and recovery can be extremely difficult, and production may be suspended for several days until the clean room can restart operations. But now, with the visualization of data and the setting and issuance of alarms that take into account facility characteristics and operational performance, we can proactively respond to any abnormal situation. We are confident in our manufacturing environment and our ability to deliver high-quality products to our customers."

-- What do you plan to do next?

"We are only at the starting point with the introduction of the OpreX EMS. We have many challenges, for example, the need to train personnel so that they can widen the use of this system by linking it with data from other systems."

"Ideally, not only utility and maintenance personnel but also operators on the production line should be looking at this data and be able to respond immediately when they sense that an anomaly is about to occur. I believe that being able to operate at that level could be a motivating factor for operators. We must make effective use of this data and share knowledge with each other."

-- We really like your corporate philosophy.

"Thank you. Our corporate philosophy of aiming to be a good company, not just a big company, is easy to understand and identify with. We also emphasize seeing things from others' standpoints, and this is something our employees try to put into practice on a daily basis in our dealings with each other, our partners, and our customers."

-- What are your expectations for Yokogawa?

"I believe that when Yokogawa upgrades its products, it takes into consideration the need to comply with the latest regulations and meet various user requirements. We are interested in seeing solutions that are based on the latest trends and pharmaceutical industry needs, and towards this end will remain in close contact with Yokogawa."



(From left) Mr. Komada, Mr. Kiyomoto, Mr. Okabe, Mr. Hasegawa

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