

# New products created from business development that leverages our unique strengths in "Measurement, Imaging, Analysis, Diagnosis, Integration"

## Environmental monitoring system provided by YOKOGAWA

Yokogawa Electric began offering the environmental monitoring system "OpreX Environmental Monitoring System" (hereinafter, OpreX EMS) for the pharmaceutical and medical device industries in October 2020. OpreX EMS, which was launched simultaneously domestically and overseas, is based on customers' needs, such as regulatory compliance, diversification of operational risks, and high usability. When asking the person in charge about the development history and features of the product, it was found that it is a new solution that meets the company's business vision.

### Life innovation business vision

Yokogawa Electric launched the Life innovation division in 2018 in order to contribute to one of its sustainability goals of "ensuring Well-being (quality life for all)."

"The business vision of the Life innovation business is to support people's safe and quality life through realizing a productivity revolution in the pharmaceutical, food, beverage, and biotech industries by leveraging our strengths of "Measurement, Imaging, Analysis, Diagnosis, Integration" throughout the entire value chain from basic research to development, production, and logistics," said Mr. Konishi, head of the Consulting Department in the same division. (Figure 1)

### New products created from unique strengths

OpreX EMS, developed as part of this business development, truly embodies our strengths "Measurement, Imaging, Analysis, Diagnosis, Integration" mentioned by Mr. Konishi.

Mr. Kubota, in charge of development, explained the development history. "In environmental monitoring, "record-taking" has a history of starting with handwriting and becoming paperless via chart recorders. As it becomes paperless, compatibility with computer becomes necessary. In addition, in recent years, with systematization the need to integrate control has arisen. OpreX EMS was developed for more expansive development of products and achievements thus far in line with these technological advances and customer needs."

Traditionally, the company's recorders have been used by many pharmaceutical companies and have been highly appreciated for their "measurement" function.

OpreX EMS is a solution that leverages this experience while further promoting the "monitoring function" as a monitoring system that responds to regulatory changes and technological advances.

In addition, by integrating and deploying products such as recorders, which have been used uniquely in each phase such as basic research, development, and production, as an environmental monitoring system, it is a product that "integrates" the entire value chain.

Especially in the manufacturing field, the company is planning to develop standardized interfaces with its own MES and LIMS.

### Environmental monitoring system with support from one recorder - supporting risk diversification and regulatory compliance

The advantages of OpreX EMS, a system that consolidates and manages recorder data on a server (Figure 2), are that "Since the system is built with recorders as base and can be deployed on a scale that meets the needs of customers, from single use to combining many recorders.

Also, because recorders can be installed in a distributed fashion across rooms and floors, they can prevent network failures and maintenance from impacting the entire system," says development officer, Mr. Minami.

It is also compatible with national data integrity guidance and FDA Part11, achieving both regulatory compliance and practical risk-diversification.

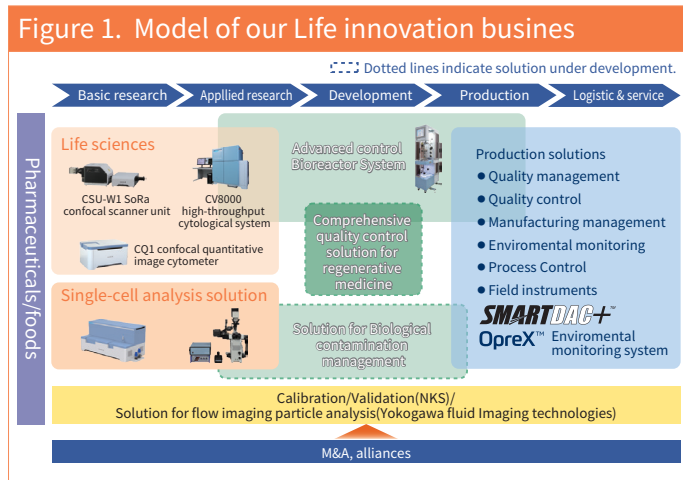
### Regulatory compliance and seven-language data acquisition control system

As mentioned earlier, the recorders used in OpreX EMS have been used in many ways.

"From the recorder launched in 2001, which is equipped with electronic records, electronic signatures, logical security, and audit trail functions compatible with FDA Part11, and is used by many customers.

Recently, there has been an increasing demand for enhanced security for recorders in order to respond to customer data integrity.

In response to this, we began offering these products in December 2019 after enhancing the functionality, such as enabling the setting of more detailed access privilege, of our data collection control system 'SMARTDAC+ (GX, GP, GM10) \*1.'" said SMARTDAC+ product planning leader, Mr. Sakagami.



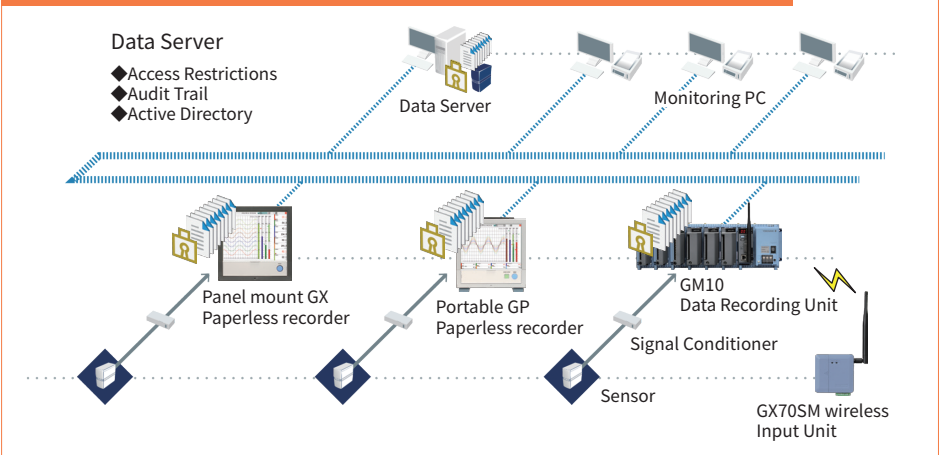
Besides regulatory compliance, SMARTDAC+ supports seven languages\*2.

"If inspectors request disclosure of data, it is necessary to present it quickly. However, since SMARTDAC+ supports seven languages it can quickly present the data in the required language and I believe that the benefits are also significant from the user's point of view. This function was incorporated as a result of greater pursuit of customers' value and merits of using it on-site," Mr. Konishi added.

\*1. SMARTDAC+ is a line-up of OpreX Data Acquisition

\*2. Data servers are currently available in two languages and will be available in seven languages in the future

Figure 2. System Configuration of OpreX Environmental Monitoring System



### Advantages unique to radio communications devices

High on-site usability is also excellent for the 920MHz band radio communications device series "SMART 920", which is an extension device of SMARTDAC+.

Mr. Fujii, a product development supervisor, talks about series' usefulness, saying, "SMART 920 is a group of products that combine main units, relay units, and remote units, such as recorders, data loggers, and power monitors. For example, the battery-powered wireless input unit "GX70SM", which is used as a remote unit, has the unique wireless advantage of being able to reduce logger placement costs required in a wired system and to flexibly cope with changes in placement of devices and the like. Recently, the importance of temperature control has increased according to the GDP guidelines, so it is introduced more and more in storage warehouses."

The 920MHz band has the characteristics of long range radio waves and great reach around obstacles, and it boasts communication distance of approximately 1 km in line of sight.



From Left, Mr.Toshihiro Fujii, Mr.Masanori Sakagami, Mr. Hiromasa Mishima, Mr.Kota Tsuji, Mr.Masaru Konishi, Mr.Yuuichiro Minami, Mr.Keiji Kubota

### Instrument calibration and validation system to accommodate a wide range of calibrations, regardless of model and manufacturer

So far, we have been looking at the features of OpreX EMS, the company offers not only products and solutions, but also a supportive system for validation and calibration.

Mr. Mishima of NKS Co. Ltd, which specializes in the validation of facilities (qualification) and the calibration of instruments and meters in the Life innovation business of the Yokogawa Electric Group, says, "We support a wide range of engineering operations for OpreX EMS as well as instrument calibration and validation of equipment."

NKS has a wide range of support systems that are rare in the industry. They not only provide equipment associated with OpreX EMS, but also performs calibration operations for approximately 700 models, regardless of manufacturer or model.

"We are working to add value to our products by supporting our customers throughout the entire life cycle through maintenance after system delivery and calibration of diverse models" (Mr. Mishima).

Centered around "measurement" with its abundant track record, they will integrate "imaging, analysis, and diagnosis" functions in systems that meet changing needs, provide solutions across departments, and "integrate" the entire system through calibration services that are not restricted to specific instruments.

In the characteristics of OpreX EMS, the company strengths of "Measurement, Imaging, Analysis, Diagnosis, Integration" as explained by Mr. Konishi above were strongly felt.

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