Technical Note

2021.04

Quality Control with X-ray inspection data Part 2 of 2

IoT support solution for X-ray inspection systems

IoT: The Internet of Things can help to improve quality and productivity in a variety of areas. As the IoT wave spreads to the pharmaceutical industry, it is expected to serve as a means of solving a variety of issues. We will discuss the current status of IoT in the industry and solutions based on inspection data from an X-ray inspection system.

What is IoT?

IoT allows a variety of devices, including PCs and smartphones, to connect to the Internet and to share information between them and control each other, thereby bringing about new value and convenience. IoT is increasingly being used in many fields, including the automotive industry, the electrical equipment industry and agriculture, bringing benefits such as visualization of processes, improvement in productivity, and standardization of work procedures by converting know-how into data.

Current status of the pharmaceutical industry

Today, proper electronic data management practices on the production floor are essential in the pharmaceutical industry. In Japan, the ER/ES Guidelines are in place, which are referred to as the Japanese version of Part 11, and requirements for replacing data in paper form with electronic data have been developed. In addition, the UK MHRA and US FDA have intensified the monitoring of data integrity (DI) activity and made data management more strict. DI guidelines require that data be in compliance with the ALCOA Principles or ALCOA Plus. Compliance with the guidelines is an important issue for the Japanese pharmaceutical industry. IoT-based data management is necessary to comply with the guidelines.

What is DI?

DI is an abbreviation for data integrity, and refers to recorded electronic data that is complete, consistent and accurate. A missing operation or transcription error may occur when converting records in paper form into electronic data. IoT is increasingly expected to be used as a means of complying with the DI guidelines.

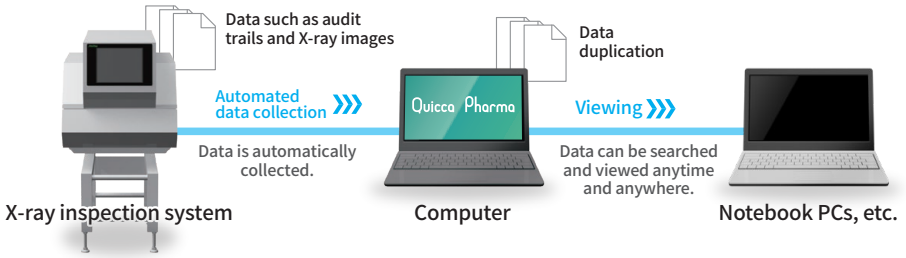
ALCOA and ALCOA+

ALCOA	A	Attributable	Who did what and when and why they did it can be determined later.
	L	Legible	All information should be readable and decipherable.
	C	Contemporaneous	Evidence of an operation, event or decision should be recorded upon its occurrence.
	O	Original	Original records should be kept and verifiable.
	A	Accurate	The accuracy of data records has been validated.
ALCOA+ (ALCOA principles with the addition of the description in the right column)		Complete	Make sure that everything is included and that nothing is missing.
		Consistent	There are no inconsistencies in the records.
		Enduring	Make sure that records are kept and protected.
		Available	Records should be available for use when needed.

● Anritsu's IoT solution

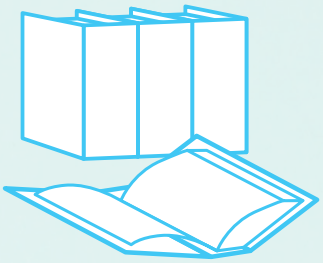
We would like to introduce you to a QUICCA Pharma-based IoT solution that makes it possible to use inspection data more effectively by connecting inspection devices scattered throughout the production floor to a system. QUICCA Pharma is an IoT system suitable for the pharmaceutical industry, and offers standard capabilities to save and output data as well as the capability to support productivity improvement and utilize recorded quality data.

Example of the QUICCA Pharma system



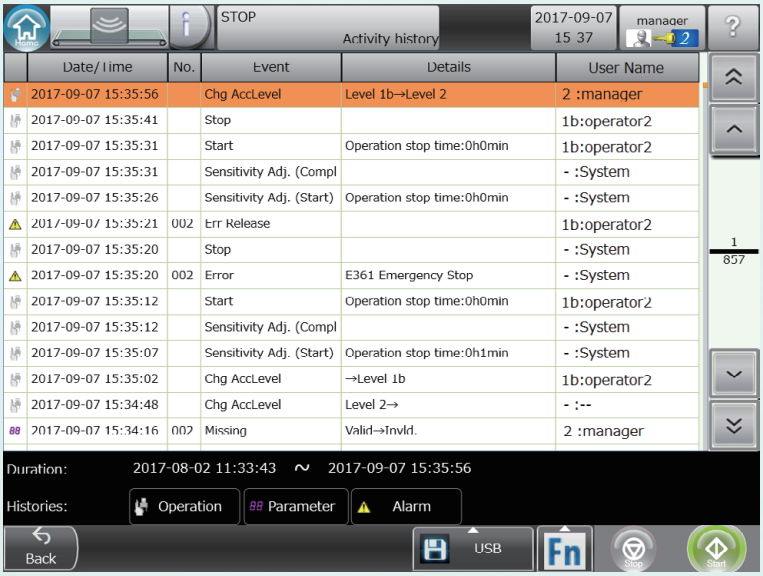
Audit trail management

An audit trail, which is a record of who operated the inspection system along with when and how, is subject to inspection by an organization like the PMDA. The reliability and accuracy of the record must be verified.



Generally, as an audit trail for an inspection system, forms printed by a printer are bound and managed, and daily operation records are saved. Consequently, a massive amount of records is created, making it laborious to find records for a specific period when presenting the audit trail to an organization like the PMDA. Furthermore, standard work procedures must be submitted to verify that records are correct.

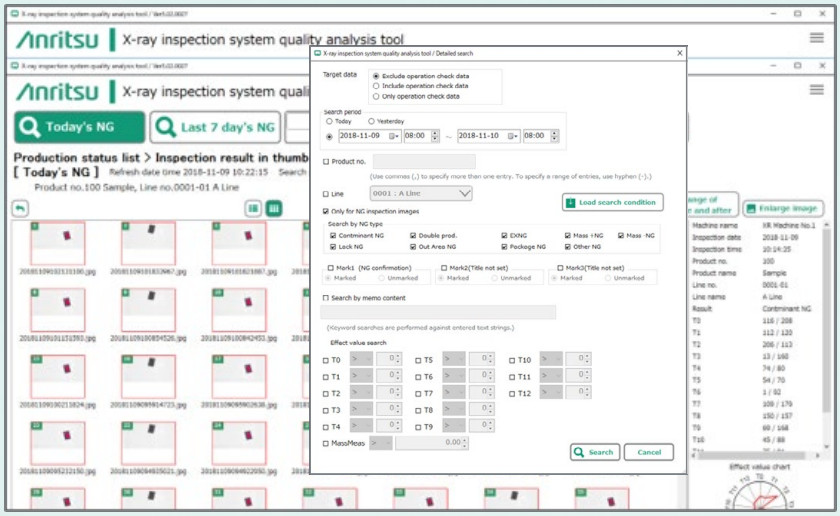
With QUICCA Pharma, an audit trail for an X-ray inspection system is automatically recorded in a manner that meets DI requirements, making it possible to view it on the PC. Audit trails for about 10 years can be saved in the system. In addition, its search capability allows audit trails for a specific period to be easily searched. Audit trails throughout the life cycle, from installation to disposal, can be easily viewed anytime and anywhere.



In addition, audit trails for all inspection systems are recorded in QUICCA Pharma, making it possible to compare data. QUICCA Pharma can be used to determine whether a deviation event in one inspection system occurred in other inspection systems. In addition to inspections, it can be used as a tool to increase safety and security.

Handling customer complaints

In recent years, with increased consumer awareness of quality and increased risk of spreading information through social media, handling complaints promptly and properly has become essential. For complaints about foreign matter contained in products, comparisons between X-ray images of products taken during inspection and those of foreign matter alone allow for confirmation that the foreign matter does not come from the production line. In these complaints-handling processes, time is needed to search the data. However, the use of QUICCA Pharma makes it easy to search data and to handle complaints promptly.



X-ray images are displayed in thumbnail view. If any foreign matter is detected, images of the NG product as well as of those before and after the product are displayed, making it possible to visually check for small foreign matter that the equipment cannot detect.

Conclusions

The use of QUICCA Pharma and an X-ray inspection system makes it easy to record an audit trail and handle complaints. IoT technology has made X-ray inspections more convenient and advanced, including the visualization of downtime, early detection of unusual conditions and notification-based improvement in production efficiency. If you have any questions about IoT or want to know more about its use, please contact us.

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