Development of QUICCA3 Total Product Quality Management and Control System Supporting Food and Pharmaceutical Production Line Analysis and Upgrades

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[Summary] The QUICCA total product quality management and control system collects inspection machine results and logs in realtime for output either to a PC screen or to a quality report and is used for quality assurance at inspection processes on foodstuff and pharmaceutical production lines. In this reported development, we worked with customer partners using developed prototypes to confirm actual introduction effects while adding new production and quality-analysis functions. As a result, the new system supports actions on improvements to solve production line problems, while also helping save labor and improving profitability.

1 Introduction

Foodstuff and pharmaceutical mass-production lines have introduced various inspection processes and machines to implement strict quality checks preventing shipment of defective products and cutting the risk of product recalls. Inspection machine results are utilized as quality records by transferring screen-displayed values to report logs and by attaching built-in printer output results to reports. However, due to consumers' increasing quality requirements, quality assurance is becoming more complex and advanced, while shortages of experienced workers is making quality management operations more difficult.

To solve these issues, 10 years ago, Anritsu developed the QUICCA total product and control system to collect inspection machine evaluation results and history logs, etc., in realtime and output quality records to a computer screen (PC) and to reports, etc. The current QUICCA2 iteration has been introduced on many production lines where it has made good contributions to product uniformity but due to the functional focus on quality management, the system is unable to provide information needed by customers to discover production line problems and to improve production based on this information. Consequently, this time we have developed QUICCA3 with added production and quality functions while working jointly with customers during prototype development to confirm the introduction effect. The new system uses IoT (Internet of Things) technology to monitor, analyze and utilize data to not only improve quality and production but also to save labor and improve profitability.

This article introduces QUICCA3 first and then explains the machines used in the inspection process, and outlines the system and inspection issues in section 2. Section 3 describes the QUICCA3 development concept for solving issues, while section 4 explains the functions, and section 5 introduces some prototype development examples and describes the introduction effect.

2 Detection Issues in Food and Pharmaceutical Industries

2.1 Inspection Machines

Typical inspection machines are checkweighers for weighing and selecting combined product weights, and metal detectors and X-ray inspectors for detecting and removing contaminants in products.

The checkweigher (Figure 1) is used mainly on foodstuff and pharmaceutical production lines for measuring the mass of each manufactured product and rejecting under or overweight products using a downstream selector. The purpose for introducing a checkweigher is not just to check weight and reject out-of-specification heavy or light products; it is also to control feedback to the product filler to minimize filling losses as well as to manage production by collecting data and to monitor for line abnormalities, making the checkweigher a key part of the production line.

Figure 1 SSV Series Checkweigher

The metal detector (Figure 2) detects the presence or absence of metal contaminants in products using changes in the magnetic field. Detection targets are limited to metals, but due to the simple construction, the price is low and the size is relatively small.

Figure 2 M6-h Series Metal Detector

The X-ray detector (Figure 3) is used to monitor food products by using X-rays in the same manner as medical X-ray machines; it can detect the presence of various foreign materials, such as metals, glass, and plastics. Inspection using a metal detector is relatively difficult but since it can detect stones, glass, bone, plastics, etc., it is in widespread use for contaminant detection purposes. In addition to contaminant detection, X-ray detectors are also used for checking for missing and broken products using X-ray images to confirm the shape of products, which is a big difference in usage from conventional metal detectors (Figure 4). In comparison to metal detectors, although the X-ray detector can detect non-metallic contaminants, the running cost is high due to the need to change the consumable X-ray source periodically.

Figure 3 XR75 Series X-ray Inspector

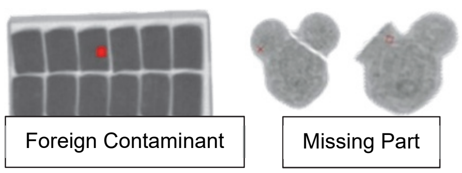

Figure 4 X-Ray Transmission Images

2.2 About QUICCA

QUICCA is a system for collecting inspection results and history logs in realtime from networked inspection machines for output to PC screens, reports, etc.

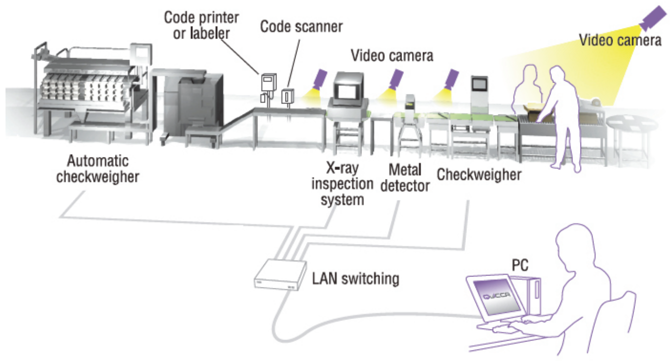

Figure 5 QUICCA System Configuration Example

From 2007, functions supporting HACCP (Hazard Analysis and Critical Control Point) management of metal detectors have been deployed to capture market requirements along with traceability functions using labelers and code readers as well as addition of video recording functions using video cameras. In particular, many plants introduced quality assurance systems to save all inspection measurement results and help suppress post-shipment product quality claims by customers.

2.3 Inspection Issues

In response to recent concerns about food safety and security, general consumers have become much more conscious about these issues. In particular, contamination of food products with foreign materials presents serious and real risks to consumers' health, resulting in total product recalls, production stoppages, and major financial damage to foodstuff manufacturers. Moreover, negative information spreads instantly over SNS (Social Networking Service), causing loss of social trust between manufacturers and consumers if the wrong initial response occurs, putting companies into continuous jeopardy.

To prevent shipment of faulty products, foodstuff makers strengthened their quality assurance systems and rules but continued to receive higher quality requests from consumers, requiring increasing and more difficult responses to quality management. For example, shipped inspected products required quality records as evidence of correct inspection. These quality records covered statistical records about total inspection counts for inspection machines, numbers of OK products, numbers of NG products, etc., as well as Critical Control Point (CCP) records covering sensitivity confirmation results for foreign-contaminant inspection machines. These quality records are recorded by on-site workers, resulting in forgotten records and record mistakes. Foodstuff manufacturers responded by improving quality assurance management through strengthened training of workers and standardized work procedures, but shortages of experienced labor as well as lower retention rates for production-line workers are causing problems with quality assurance operations using people. Additionally, rising cost of labor and raw materials require improved productivity to maintain margins.

Against this difficult background, various factory equipment is being switched to IoT specifications and there is increasing investment in these data information systems, which demands further development of the Anritsu QUICCA system.

3 Development Concept

3.1 QUICCA3 Concept

To solve inspection issues in the foodstuffs and pharmaceutical business worlds, we have developed QUICCA3 based on the following four concepts.

(1) Visualizing quality assurance information

Quality assurance data such as inspection equipment statistics, faulty product and error occurrence status, histograms and Xbar-R management figures can be confirmed simultaneously both in the production plant and at other locations. This enables each user to recognize the situation and respond quickly.

(2) Improving production efficiency through data analysis

Deviation in inspection equipment operation rates and inspection results can be quantified for index-based analysis to provide information linked to identification of remedial action. In this way, customers do not waste daily work time for analysis, and problems can be solved effectively for lines with decreasing productivity for which customers do not have effective countermeasures; the analysis results can be output to reports.

(3) Advancing and expanding CCP management applications

To validate inspection-equipment CCP actual records are output to forms. The operation confirmation required by CCP management is implemented at fixed time intervals before, after and during production. With the increase in CCP-specified items, X-ray inspection machines are also coming under CCP management. Reports containing X-ray transmission images, statistics, and operator information are used as reliability evidence for monitoring and warranty claims.

(4) Reducing risk of shipping contaminated products by maximizing use of inspection equipment

The risk of shipping fault products can be reduced by confirming the detailed inspection machine settings and inspection results. X-ray inspection equipment can be used to check products with potential for contamination by foreign materials.

3.2 Prototype Development

Quality assurance requirements using inspection machinery inspection results require consideration of many common points that are not limited to the type of industry or type of machine. As a result, future development to add functions solving quality assurance issues requires listening to customers' opinions and observing on-site production.

However, despite having the same objective of improving productivity, analysis involves many different procedures at each plant due to differences in product types, manufacturing methods, production amounts, etc., making it difficult from the inspection equipment manufacturer's perspective to develop functions on-site.

Consequently, in this development, we worked on prototypes in conjunction with partner customers to solve problems. At prototype development, we first listened to the customers' annoyances to establish the issues, define the needs, offer, evaluate and improve the prototype in a virtuous cycle to provide useful functions. This prototyping method was repeated with multiple customers to add standard functions to QUICCA3 tuned to customers' production analysis ideas.

3.3 IoT Introduction

IoT technology is being adopted to visualize production management data. IoT is the acronym for Internet of Things but the essence of IoT is not connecting 'things' to the Internet. The basis of IoT is collection of data on equipment, including inspection machinery, from the production site, visualization of this collected data, and analysis and use of the data shown by the following steps.

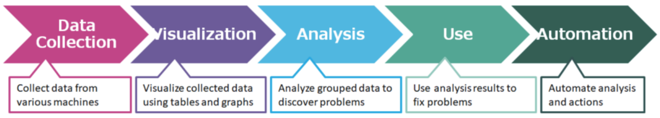

Figure 6 IoT Introduction

Electrical equipment and automobile makers are rapidly introducing IoT technologies to promote global development but the foodstuff and pharmaceutical businesses are not yet at this IoT expansion stage.

One reason why IoT introduction is not progressing rapidly is the difference in data collection methods by each machine; there is a lack of people who can narrow-down the many issues in visualizing the overall plant systems and in understanding plant systems production line status and requirements.

QUICCA3 targets all functions from data collection to actions to simplify introduction of IoT to production lines.

4 Function Introduction

4.1 Basic Functions

The first QUICCA 'visualization of production management information' concept, or in other words simultaneous confirmation of production management information on-site and elsewhere, means adding functions for collecting information into a database on a web server that can be accessed through a web browser portal. Observation of data in a database created on a web server using a web browser is an excellent method for simultaneous monitoring by many people at various locations on the network. The web browser can run on a PC or a smartphone and there is less resistance to usage because web browsers are now commonly used information technology (IT) in both business and private scenarios.

On the other hand, management of production information over the Internet raises many issues about data safety and security. As a result, the web server runs on the PC where QUICCA is installed and is designed for use of functions without an Internet connection.

4.2 Web Browser Use

The following sections describe visualization of production management information with examples of analysis and use.

(1) QUICCA Web Function

This function has a screen (Figure 7) with a simple list of the status of inspection machines in the plant.

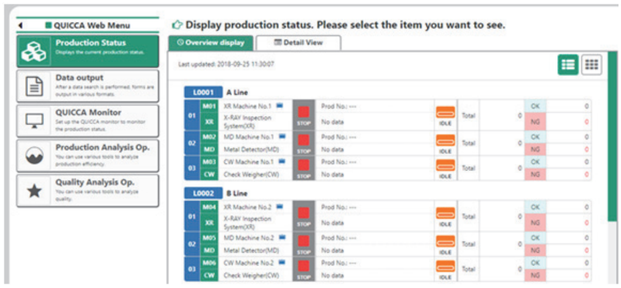

Figure 7 QUICCA Web Screen

It lists information such as inspection machine conveyor On/Off conditions, the production of goods on each line and the number of OK and NG items, etc. Data can also be output from the screen and up-to-date product quality data output at a printer can also be output as PDF files (Figure 8). Since quality managers can immediately confirm the inspection results on their own PC for lines where production has finished and can also leave a PDF file of quality records, paperless quality assurance systems can also be implemented.

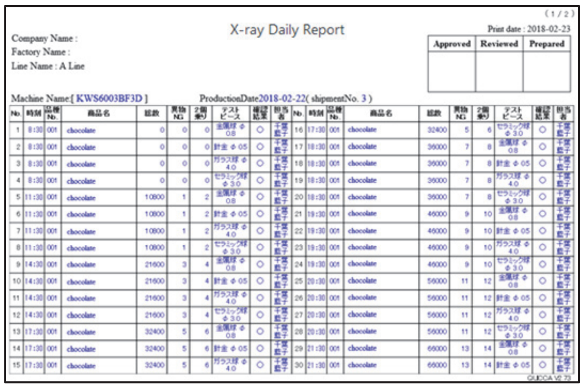

Figure 8 Quality Data (CCP Management Log)

(2) QUICCA Monitoring Function

This function displays part combinations visualizing the production management information in a variety of formats (Figure 9). Since plant and quality managers as well as operators can confirm the production information both within the plant and from other locations, it facilitates quick evaluations.

Figure 9 QUICCA Monitor Screen

The above figure is an example showing information such as the masses of products captured from a single checkweigher and the OK/NG evaluation status in various formats, helping managers and operators immediately grasp dispersion in measured masses, NG product rates, etc., and giving a direct impression of production trends. Production management information can be understood from both numeric and graphical visual representations, helping operators recognize the line conditions to adjust fillers so masses satisfy upper limit trends and NG rates exceeding normal levels can be linked with autonomous actions.

(3) OEE Monitor Function

This function analyzes production management information and visualizes production rates. QUICCA3 uses the Overall Equipment Effectiveness (OEE) index for analysis production rates; the OEE is a numerical index (Figure 10 and 11) related to the infrastructure operation rate and is determined as follows.

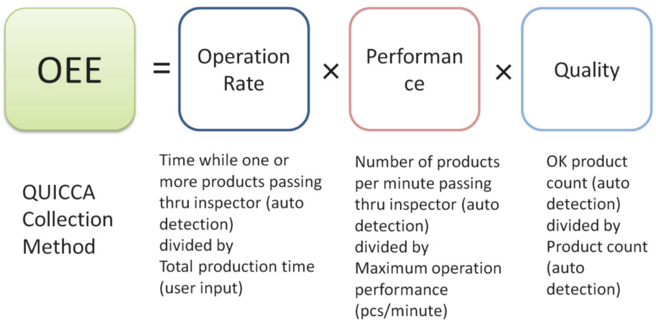

Figure 10 OEE Calculation

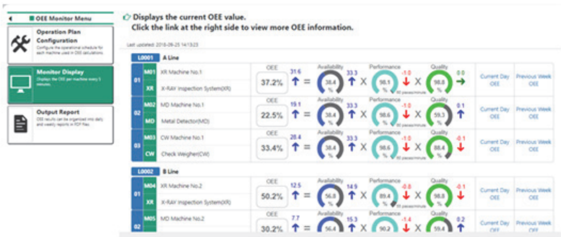

Figure 11 OEE Monitor Screen

When the plant manager wants to increase plant productivity, this function can be used to improve the production rate of lines with a low OEE, or it can be used to evaluate materials when wanting to increase the number of lines. Furthermore, using this function, anyone can evaluate the performance rate from the numbers instead of depending on expert impressions about the impact of improvements.

4.3 X-ray Inspection Results

The X-ray quality analysis tool supports quality assurance by using X-ray transmission image results saved from all X-ray inspection machines. Using this tool supports operation by lowering output of contaminated products.

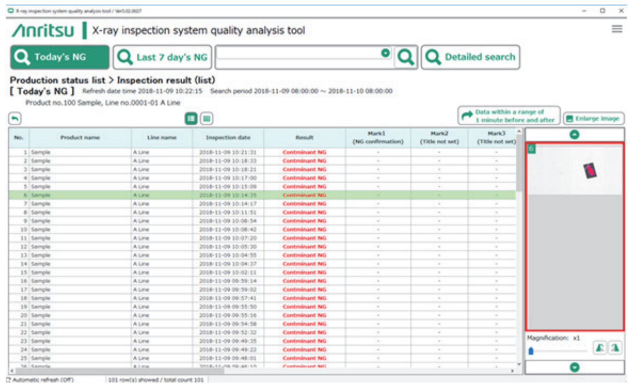

Figure 12 X-ray Inspector Quality Analysis Tool

By using this tool, the days when NG products start occurring on the line are extracted automatically. This supports easy visual checks of NG images by the quality inspector before shipping. For example, the risk of shipping contaminated products can be lowered because the presence/absence of foreign materials, such as parts like nuts and bolts from the plant, can be confirmed by displaying X-ray images of OK products that may contain very small contaminants with low detection sensitivity.

Additionally, this tool can be used when confirming the possibility of shipping contaminated products in a production time band when receiving a claim from a customer about a possibly contaminated product. Generally, confirmation work requires a huge amount of time to check many tens of thousands of images one-by-one just to confirm that no product was shipped containing a contaminant similar to that in the claim. The search function in this tool makes this search work much more efficient. Setting search conditions, such as the specified time band and NG results for a line can help find detection results similar to the claimed contaminant, greatly shortening the time required to investigate the claim.

4.4 Pharmaceutical Inspection Machines

Selling pharmaceutical products in the global market first requires compliance with national rules and guidelines regarding collection and recording of electronic data like those specified by the Data Integrity rules of the US Food and Drug Administration (FDA). The DI rules require that all collected data is correct and consistent throughout its life cycle. As a consequence, Anritsu inspection machinery destined for the pharmaceutical business world is in full compliance with the DI requirements and saves records such as the date and time of setting changes, operator's name, etc., as inspection evidence within the inspection machine memory.

The inspection evidence is the target for FDA review requiring specific records that must be correct. The inspection machine inspection evidence is commonly managed by attaching printed paper output to records but this leads to huge volumes of daily paper operation records that must be preserved for long time periods. As a result, showing inspection evidence to the FDA requires large amounts of time and effort searching for records in the specified period, while explanation of the correctness of these records demands management procedures such as sealed record submission and specific standard working procedures.

The QUICCA Pharma version of QUICCA3 released for the pharmaceutical business world collects the inspection machine inspection evidence using a fully automated system that can reference inspection evidence for all machine life cycles from introduction to final disposal. The search function can quickly recall inspection evidence for the time period specified at the FDA review and system records and outputs from the system. Additionally, data can be compared because inspection evidence for all machines is recorded in the system, leading to creation of a new system for improving quality by confirming that deviations from the norm did not occur for a certain machine.

5 Prototype Development Examples and Introduction Issues

This section introduces some prototype development examples and their improvement effects.

5.1 Cutting Unnecessary Raw Materials

One example of interest to customers is improving profitability by cutting unnecessary wastage of raw materials. Wastage occurs on production lines because operators are worried about producing underweight products that must be rejected. Even if the production manager explains wastage of raw materials to workers using histograms created with Excel spreadsheets, it does not lead to improvement unless the workers see the concrete impact of making adjustments.

(1) Prototype Development Examples

First, QUICCA3 automates the time-consuming effort of creating histograms using Excel. The difference between the target adjustments based on histograms created automatically for the morning meeting and the actual numeric values may be communicated but this information is not linked to concrete actions of operators. If histograms can be displayed in realtime to operators, improvements are achieved because operators can adjust fillers at the same time as confirming the numeric results.

(2) Introduction Effect

Displaying histograms on tablet terminals clarified drift in current target masses and filler adjustment ranges. As a result, operators could adjust the fillers while considering dispersion while watching the handheld monitor to confirm the results. Visualization increases operators consciousness of unnecessary waste and raises profitability by continually cutting wastage of raw materials through motivation to make adjustments (Figure 13).

Figure 13 Histogram Usage Examples

5.2 Confirming Labor-Saving Production Progress

This example covers customers' issues with wanting to save labor at confirmation of production yields. Production managers commonly record confirmed OK product counts for lines on an office whiteboard, which they use for managing yields. When workers move from the line to the office, they often pass through an air shower and into an area for hand washing, etc. When confirming production yields, these daily passages back and forth take time and incur production costs. In addition, yields may be neglected on lines with large spare production target margins, and large completion delays may become evident.

(1) Prototype Development Examples

At first, the production yield based on the production plan and OK product count, which have been input before starting work, might be displayed on a large monitor. At the first iteration, all the information about the product name, OK product counts, etc., are displayed in the same font size, but the re-design adjusted for easier recognition of the presence or absence of delays, drawing attention to important factors, such as missed counts.

Moreover, for customers producing small lots, it is obviously difficult to establish early production plans due to changes in shipping counts during production. Consequently, to simplify production changes, improvements were made so as to output only actual production yields even without production plans.

(2) Introduction Effect

By displaying production yields using OK products on a large monitor, it is possible to understand yields in realtime even at the office, helping cut costs associated with yield confirmation. Moreover, it became easier to predict the time when production would be completed, helping make preparations for the next production run more efficient (Figure 14).

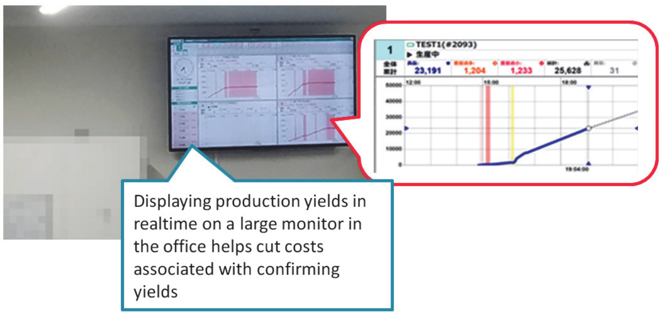

Figure 14 Production Yield Visualization Example

6 Conclusions

We developed QUICCA3 as the latest total product quality management and control system. To match customers' requirements, development was executed using prototypes for multiple customers. As a consequence, we were able to improve foodstuff and pharmaceutical production line productivity from viewpoints other than inspection machine performance and functions. Against the background of globalization and labor shortages, we expect to continue future research into products satisfying the requirements for higher productivity and assured product quality.

References

1) Atsushi Iida, Junichi Tamura, Kenta Yamada, Kohei Suzuki, Hironori Sato, Takamasa Ito, Hirotaka Anzai, Mark Bajo: Development of SSV Series Multilane Checkweighers, Anritsu Technical Review No.27 (Sep. 2019)

2) Takashi Kanai: Principle and Use of Inspection Systems for FoodContaminants, Anritsu Technical Review No.22 (Sep. 2014)

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