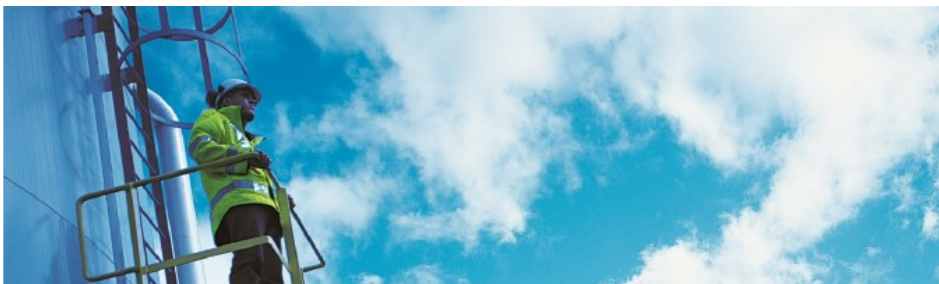# Application Note

Take the pain out of compliance with automated tracking of batch data with Exaquantum/Batch

Effective solution to improve production efficiencies

Businesses that operate in the pharmaceutical industry, like many of the process industries, are required to drive continuous improvement programs with the aid of new technologies and systems in a highly competitive market. To boost productivity and efficiency, they implement strategies to increase the availability, reliability and sustainability of their systems, improve maintenance and traceability.

To successfully adopt this approach, organizations demand a flawless manufacturing process that can operate across multiple function areas to enable business evolution and provide enhanced control and greater flexibility. The challenge for many businesses is how to improve production and increase the quantity of goods produced.

A pharmaceutical company based in Europe, who mainly produces salicylic acid and derivative products using chemical processes, wanted an effective solution to improve their production processes and efficiencies. For greater insight, reliability and traceability, they required a solution that encompassed the whole production system including the distributed control system (DCS), the manufacturing execution system (MES) and a batch information system. Importantly, the complete batch system had to conform to ISA-88 batch control standards, providing information on batch quality with a more agile DCS platform to enable greater flexibility in the quantity of products being produced.

The plant consists of two main units, one with a continuous process to produce the salicylic acid, and one batch process to produce value-added products. Like many organizations in the pharmaceutical industry, the plant must comply with the Food & Drug Administration (FDA) regulations, including the 21 CFR Part 11 section on electronic records and electronic signatures. This sets out the criteria under which the processing of this electronic data are considered trustworthy, reliable, and equivalent to paper records. In addition to meeting these regulations, accurate tracking of process behavior, quality and quantity of products was to be included in the project requirements for reliability and traceability across the entire scope of the control system.

Batch data that complies to 21 CFR Part 11

With considerable experience and knowledge across all production systems combined with an extensive regional install base, Yokogawa successfully proposed and installed a complete control system solution. By installing a new process control system, replacing the existing system that was based on relay circuitry and PID controllers, it provided the necessary features to simplify the quality and production reporting and monitoring requirements. This new DCS system enables better operational management with increased availability, reliability and sustainability that conforms to FDA requirements concerning validation and follow-up requirements.

For information on the batch production system and to meet the regulations for 21 CFR Part 11, a batch monitoring solution was included as part of the batch control system solution. Exaquantum/Batch is an intelligent and scalable ISA-88 batch information system for analysis and reporting. For projects that include CENTUM DCS for batch processes, it is an ideal partner, offering 'out-of-the-box' integration and provides immediate usability and benefits without complex engineering and database configuration providing valuable information and insight for producing the value-added products.

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Phased Deployment Approach

The ultimate goal for this project was to deliver improved production and increase the quantity of goods produced. By dividing this migration project into two phases, it allowed a smoother integration with the transfer of the batch unit first, followed by the continuous unit.

PHASE 1

Yokogawa's Exaquantum/Batch was implemented first and integrated with the DCS Batch control application (CENTUM VP Batch). The main reason for this is two-fold. It was critical that the control room could access the batch data from the batch historian via a single web client. Second, to monitor and record activities, Exaquantum/Batch with in-built and automated reporting functionality that adheres to the ISA-88 standards, it provided information on all batches, including model validation and modification tracking.

PHASE 2

The scope of the CENTUM DCS control layer was extended to cover the continuous processes units. With the valuable information and insight that was being generated in the batch process, it was decided to extend the installed Exaquantum server to allow external access from the office in a secured environment to oversee manufacturing across both production units.

What are the Benefits?

With the first phase solution deployed and operational, batch production was now managed and maintained more effectively. With enhanced batch monitoring and analysis capabilities, the availability and reliability of their systems are greatly improved. With the long-term historian data access and automated reporting capabilities, it provides a sustainable solution platform to improve production and increase the quantity and quality of goods manufactured.

This facilitates a much improved production and quality workflow. Previously, much of this information was being produced manually with paper-based workflows that was both time consuming and decentralized. It became laborious to manage, relying in part to some human intervention and therefore difficult to achieve the targets for quality, production and maintenance follow up. With the new solution that is more reliable and automated, production reports are generated and readily available in a centralized location that can be shared and distributed to colleagues in a time efficient manner. This is a more effective and proficient method to deliver production information without the need for human interaction.

> "It provides a sustainable solution platform to improve production and increase the quantity and quality of goods manufactured."

Project Background

Because Yokogawa was widely known to the group with several past projects with the sister companies of this organization, it provided a good basis to begin discussions to determine exactly what was required in this solution. With an extensive and successful history of previous installations in this region combined with a large knowledge base, Yokogawa were successful in being selected as the preferred partner for this project.

However, as the plant was already using Emerson solutions installed on site, with the customer being very confident with this provider, competition was aggressive and intense with very short initial budgets and delays to the schedule. It was therefore important that we fully engaged, demonstrated our commitment to the solutions and focused on the end user requirements, in complete collaboration with the customer.

With the capabilities and features provided by a CENTUM DCS, it provided a number of benefits that were aligned to the project requirements and helped to secure this project for Yokogawa. Exaquantum/Batch was included because of the close alignment and seamless integration with CENTUM VP Batch and considered as an extension to the control system when it was installed on site. It also ticked all the boxes regarding functionality that was required in the short term for tracking and reporting on batch productions.

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Project Scope

The process control platform migration replicated a similar batch and control design that utilized a CENTUM VP DCS that was successfully deployed and installed at other sites within the wider company group.

The plant information management solution (PIMS) data acquisition requisites were defined and configured during the first phase of the project, focusing on the batch processes to meet the FDA regulatory standards. These conditions were adjusted and modified in the second phase of the project when the continuous processes were introduced that were focused upon the measurement types and specific end user needs. This included extending the data historian license to incorporate the new units coming from the DCS application.

At the executive level, there were a number of reporting conditions and stipulations to improve business process and agility. Moving away from the heavily reliant manual processes to a more automated and streamlined framework with improved accessibility for staff across the organization. Automated reports were requested with both imprecise and complex specifications from the customer. Yokogawa included these, plus user accessibility, cybersecurity, with report adaptation to be considered as part of the scope of reporting requirements.

Loss of data is perhaps the number one priority in terms of data security for many businesses in the process industry. To address any concerns, Yokogawa proposed a full back-up solution of the system. This included an external off-site data gathering center on the customer side as an important and justifiable measure to significantly reduce the risk of data loss. This commitment to a total back-up solution included the DCS, Safety and PIMS systems to increase data integrity. With back-ups to help ensure data is safe from failure, users can work without worrying about the safety and security of their data and without interruption.

Implementation

To implement this project, a number of considerations and additional requirements were included. When external access was required during the extension of Exaquantum scope, there were discussions concerning architecture revisions, cybersecurity and automated back-ups. A thick client acting as Terminal Server was implemented to allow access to Exaquantum/Explorer from office terminals and a web server has been added to Exaquantum for both trends and alarms and events (A&E) data that is accessible directly from computers in the office.

The Exaquantum server and Exaquantum thick client (Terminal Server) have been implemented within a demilitarized zone (DMZ) with a trusted zone below (DCS: mainly OPC communication) and an untrusted zone above (Office network: mainly RDP access to terminal server, Web access to Exaquantum server). A Juniper physical firewall is used to configure this DMZ.

Exaquantum/Batch Report Server has been used for the automated reports. These reports appear alongside the batch reports in the web user interface (BatchWeb) and the report model management is aligned with the existing batch reports.

Cybersecurity was implemented in a consistent and logical way with DCS: global software solutions (backup and antivirus), backups (DCS databases, PIMS databases, PIMS archives, Ghosts), subdomain controller, time synchronization Office<>DCS<>DMZ.

The specific configuration was complex because of the bespoke requirements for the automated reports. These reports include specific functions, such as:

- The list of the users logged on DCS during one production day

- An automated detection and justification of process overshoots based on eight critical measurements that impact product output quality. In case of overshoot on one or several critical parameters of the process, an alarm history for the day is automatically added to the report for the particular tag. The associated overshoots and operator justifications entered in DCS are included with the alarm history.

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Key Takeaways

Integral to CENTUM VP Batch DCS projects

Exaquantum is often included as part of the DCS in proposals, but not considered as a separate entity. It is viewed as more of an add-on or additional component in the project schedule that is difficult to manage and does not utilize the full potential of a PIMS solution. By considering Exaquantum as a stand-alone solution, acting as a hub to distribute information throughout the business in various formats, it allows data to be transformed into actionable information. This project provided insight into both batch and process information that was easily adapted to meet the changing business needs that ultimately improved the end users production processes.

Agile and flexible PIMS platform

Exaquantum/Batch was required to extend the functions of the DCS, for tracking and reporting on batch productions. With the evolution of the site and the expanded requirements incorporating the continuous processing unit, Exaquantum/Batch was able to meet these additional conditions. Considered as more of a plant information management system that is both agile and flexible, it was used more like a corporate historian and monitoring tool, acquiring, storing and tracking both process and batch data. This process level information was also readily and easily accessible by office staff at the business level.

Define reporting requirements upfront

Deciding on reports, data analysis and the information delivery strategy can have a significant impact on the business processes, helping to ensure that the FDA 21 CFR Part 11 regulations and standards are adhered to. Additionally, this data can provide evidence to aid the decision making process to support the business for better operational management. The reporting capabilities in Exaquantum and Exaquantum/Batch should be defined and agreed at an early stage to ensure clarity of information and reporting outcomes. The standard configuration of Exaquantum easily allows gathering of live or historical values/aggregations with simple calculations and formatting. If reporting requirements are modified or adjusted at a later stage, it has the potential to destabilize workflows and mechanisms that could undermine project delivery and quality of the results.

System Architecture
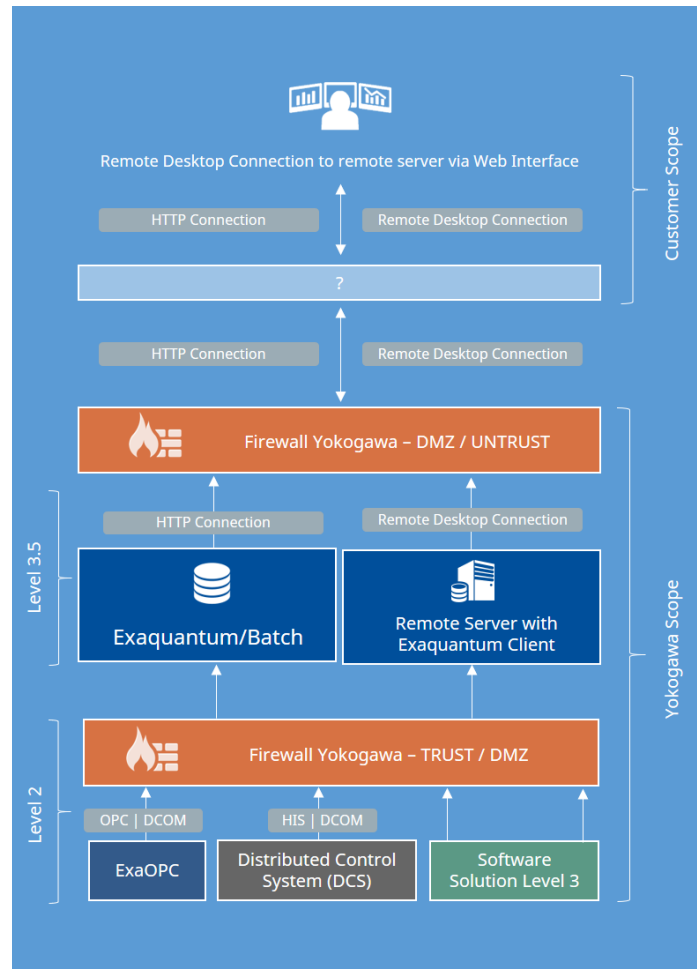
"Exaquantum/Batch is a scalable ISA-88 batch information system for analysis and reporting."

References

Exaquantum PIMS R2.85

Exaquantum/Batch R2.50.40

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