Essential Nutriments to Save Lives Made Possible by AVEVA

Baxter S.A.

INDUSTRY
Life Sciences

Goals

- Increasing production capacity while significantly reducing manufacturing throughput time was a top priority for Baxter

- The new automation system needed to assist Baxter in achieving U.S. Food and Drug Administration (FDA) 21 CFR Part 11 compliance regulations

Challenges

- The automation system selected for the new Baxter production line had to be fully compatible with Baxter's existing architecture and systems

- The company required that the new system integrate Profibus-connected smart sensors into the new manufacturing line process

- Production management had to be centralised and include reporting, analysis, traceability and performance monitoring to adhere to FDA 21 CFR Part 11 regulations as well as European compliance standards

AVEVA Solution

- InTouch

- System Platform

- Batch Management

- Historian

Results

- The implementation of the new Wonderware system doubled the manufacturing facility's productivity

- Baxter's manufacturing processes are now fully traceable and meet all FDA and European regulations

- System Platform powered by Wonderware has enabled the BiiON engineers to create approximately 35 reusable generic objects, which are stored in a central library

Wonderware by AVEVA

Background

Lessines, Belgium – The process of feeding someone intravenously involves a wide range of components and decisions. Patients and their families facing these monumental choices must rely on and trust the expertise of medical professionals and the products they choose to administer these treatments.

As a global diversified healthcare company, Baxter S.A. applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to develop products that advance patient care worldwide. Baxter's Lessines, Belgium facility is responsible for manufacturing single and multiple compartment storage bags for administering nutriments to patients intravenously. To streamline its operations, manage operating costs and conform to the U.S. Food and Drug Administration's 21 CFR Part 11 compliance standards, Baxter needed to revise its manufacturing facility processes to incorporate automation methods into a new production line.

To achieve this goal, Baxter selected Wonderware software from AVEVA to manage its new production line. Baxter implemented Batch Management for batch execution and genealogy reporting; InTouch HMI for process visualisation; and System Platform powered by Wonderware to provide a single, scalable platform for all SCADA, supervisory HMI and MES applications.
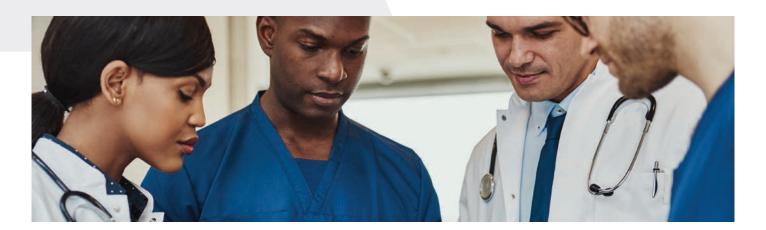
Integration of All Existing Manufacturing Process Key to Success

Baxter's new manufacturing line not only had to double the production capacity, but also had to integrate each of the facility's sub-systems to form a unified and automated manufacturing process. The new line is composed of six processes for preparing the various nutriments and filling the intravenous storage bags.

These include:

- Preparation, dilution and buffer storage of emulsion
- Dilution and buffer storage of glucose
- Dilution and buffer storage of amino acids
- Distribution of cleaning utilities (WFI, vacuum, nitrogen, etc.)
- Distribution of the three prepared solutions to the filling equipment
- Cleaning in place of the equipment

Because the company needed the new production line to interact with existing systems, the new Wonderware software architecture had to be compatible. The use of System Platform in conjunction with InTouch HMI provided Baxter with an open architecture framework that enabled the company to easily incorporate the various technologies operating in the plant.

Baxter has been using InTouch HMI for the past 10 years to provide visualisation of its plant processes. With the implementation of System Platform, the functionality of InTouch HMI has been expanded and provides Baxter with architectural integrity, unequaled device integration and connectivity, and an uninterrupted software version migration path — all of which maximises productivity and optimises user effectiveness.

System Platform is the "plant model" which provides a logical representation of the physical processes being controlled and supervised at the Baxter facility. Its object-based technology simplifies configuration, logging, delivery and maintenance of real-time and historical information.

System Platform provides a high-performance process historian with production history archiving, efficient data compression and auto-configuration of historical archiving that eliminates duplicate effort. The Historian Clients uses the web and this dramatically simplifies the organisation and delivery of operations information for use across all functions at Baxter's manufacturing operations.

"The BiiON and Baxter teams selected System Platform powered by Wonderware because of its advanced capabilities for SCADA applications and its scalability features that ensure compatibility with the existing infrastructure and future system upgrades."

Serge Bassem,
Chief Executive Officer at BiiON.

Implementation of the user-friendly Wonderware software enabled Baxter plant operators and managers to quickly adopt the user interface application and more easily manage reporting

functions. Plant management is now able to provide clear presentations of historical data, alarm and events to meet process, quality assurance and technical requirements. The existing installation was already automated by BiiON in 2002 but was based on more traditional technologies such as analog sensors and conventional SCADA. While the system included a large number of physical and software connections between new and existing lines, special attention had to be paid to interoperability.

System Integration Combined with Wonderware Software Key to Production Line Interoperability

BiiON, which specializes in pharmaceutical and biotechnology industry system integration, worked closely with AVEVA and Baxter to ensure the successful implementation of the automation process for the new manufacturing line. In particular, the installation and configuration of Historian and eSignature management applications ensures Baxter's compliance with FDA 21 CFR Part 11 regulations.

Historian provides Baxter with a comprehensive real-time database for historical information which is designed to collect a wide variety of plant data, at full resolution and at very high data rates. The collection of this important process data ensures that decision-makers at all levels have the historical information needed to drive vital productivity improvement initiatives.

A high security Web server hosts the user interface application for recipe management and configurable parameters as well as graph, audit trail and report generation. Using System Platform in conjunction with Batch Management, Baxter was able to design a custom set of ISA S88 standard compliant objects to be stored in the system's central library where they can be maintained and reused for future projects.

Batch Management is consistent with the ISA S88 flexible batching standard and offers comprehensive batch execution and equipment history, material genealogy, stringent security, web-based reporting and the ability to facilitate the design and implementation of systems that are compliant with FDA 21 CFR Part 11 regulations. These operations are interconnected via a Profibus network that allows for centralised management with a direct interface between System Platform and Baxter's existing MES systems.

"Other requirements including database interoperability, smart calculations and production report generation were easily managed by System Platform. In addition, the scalability features of Wonderware software were also a very important factor in Baxter's decision because the automation system would be evolving over time. All of these performance factors reinforced our decision to implement this vital system architecture."

Serge Bassem,
Chief Executive Officer at BiiON.

Using the powerful toolkit provided by System Platform has enabled the BiiON engineers to create approximately 35 reusable generic objects for functions such as valves, sensors, weighing equipment and variable speed drives, which are stored in a central library. Each functional object is associated with a PLC and SCADA software code. These functional objects are linked to the processes in the system so that any changes made to the generic functional object are immediately replicated with the ability to be linked to all instances in the system. The engineer maintains control on whether he wants to deploy modifications on all or part of the instances of the relevant object. This allows the engineering staff to validate modifications being implemented before making a global deployment.

Achieving FDA and European Regulation Compliance

The complete automation system, including the hardware and software that controls this new production line, is now completely implemented, validated and qualified in accordance with the current manufacturing practices defined by European and FDA regulations.

The basic needs of human sustenance are water and food for survival. Baxter's compartment storage bags play a critical role in nourishing those who are unable to feed themselves either due to illness, surgery or other medical conditions. Baxter's products are key to the success of patient care and recovery, and Wonderware software is playing an important role in successfully delivering these life-saving products.

About AVEVA

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