



CUSTOMER CASE STUDY

Baxter uses AVEVA software to double production at nutriments manufacturing facility

Baxter S.A. - www.baxter.com
Industry - Pharmaceuticals

Goals

- Increasing production capacity while significantly reducing manufacturing throughput time
- Incorporating automation in a new production line to comply with U.S. FDA regulations

Challenges

- Keeping automation system compatible with existing architecture and systems
- Centralizing production management to include reporting, analysis and traceability
- Ensuring performance monitoring complies with US and European standards

Results

- Doubled productivity at the manufacturing facility
- Manufacturing processes are fully traceable and comply with FDA and European regulations
- New generic objects library simplifies batch management

Solutions

- AVEVA™ InTouch HMI
- AVEVA™ System Platform
- AVEVA™ Batch Management
- AVEVA™ Historian

The process of feeding someone intravenously involves a 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 with 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 AVEVA solutions to manage its new production line. Baxter used AVEVA Batch Management for batch execution and genealogy reporting; AVEVA InTouch HMI for process visualization; and AVEVA System Platform to provide a single, scalable platform for all SCADA, supervisory HMI, and MES applications.

User-friendly software simplifies monitoring and reporting

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 AVEVA software architecture had to be compatible. By using AVEVA System Platform along with AVEVA InTouch HMI, the company gained an open architecture framework that could easily incorporate the various technologies operating in the plant.

Baxter has used AVEVA InTouch HMI for the past 10 years to visualize plant processes. With AVEVA System Platform, their AVEVA InTouch HMI has new architectural integrity, unequalled device integration and connectivity, and an uninterrupted software version migration path. Together, the systems are helping Baxter maximize productivity and optimize user effectiveness.

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

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

With the user-friendly AVEVA software, Baxter plant operators and managers can quickly adopt the user interface application and more easily manage reporting functions. Plant management can now provide clear presentations of historical data, alarms 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 many physical and software connections between new and existing lines, Baxter need to pay more special attention to interoperability.

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

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Serge Bassem
CEO, BiiON

Baxter partners with BiiON and AVEVA to configure new production line

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 AVEVA Historian and eSignature management applications ensure Baxter’s compliance with U.S. Food and Drug Administration’s (FDA) 21 CFR Part 11 regulations.

AVEVA Historian provides Baxter with a comprehensive real-time database for historical information. AVEVA designed the solution 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. By using AVEVA System Platform along with AVEVA Batch Management, Baxter designed 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.

AVEVA 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 centralized management with a direct interface between AVEVA System Platform and Baxter’s existing MES systems.

BiiON engineers used AVEVA System Platform 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 of 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.



“Other requirements – including database interoperability, smart calculations, and production report generation – were easily managed by AVEVA System Platform. In addition, the scalability features of AVEVA 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.”

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Serge Bassem
CEO, BiiON

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 AVEVA software is playing an important role in successfully delivering these life-saving products.