

## Baxter S.A.

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.

### Essential Nutriment to Save Lives Made Possible by Schneider Electric Software

*“To be successful, strategic projects require excellent collaboration between the customer, the software vendor and integrator. By establishing the automation framework, Wonderware software solutions enabled our project teams to focus on productivity targets.”*

**Serge Bassem** || Chief Executive Officer at BiiON (Baxter System Integrator)

#### 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 centralized and include reporting, analysis, traceability and performance monitoring to adhere to FDA 21 CFR Part 11 regulations as well as European compliance standards

#### Solutions & Products

- + [Wonderware InTouch](#)
- + [Wonderware System Platform](#)
- + [Wonderware InBatch](#)
- + [Wonderware 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
- + Wonderware System Platform has enabled the BiiON engineers to create roughly 35 reusable generic objects, which are stored in a central library



## 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 nutriment 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 Schneider Electric to manage its new production line. Baxter implemented Wonderware InBatch for batch execution and genealogy reporting; Wonderware InTouch HMI for process visualization; and Wonderware System Platform 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 nutriment 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 Wonderware 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 Wonderware InTouch for the past 10 years to provide visualization of its plant processes. With the implementation of Wonderware System Platform, the functionality of InTouch has been expanded and provides Baxter with architectural integrity, unequalled device integration and connectivity, and an uninterrupted software version migration path – all of which maximizes productivity and optimizes user effectiveness.



Wonderware 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 Information Server uses the web and this dramatically simplifies the organization and delivery of operations information for use across all functions at Baxter’s manufacturing operations.

“The BiiON and Baxter teams selected Wonderware Systems Platform because of its advanced capabilities for SCADA applications and its scalability features that ensure compatibility with the existing infrastructure and future system upgrades,” said 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 Wonderware and Baxter to ensure the successful implementation of the automation process for the new manufacturing line. In particular, the installation and configuration of Wonderware Historian and eSignature management applications ensures Baxter’s compliance with FDA 21 CFR Part 11 regulations.

Wonderware 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 Wonderware System Platform in conjunction with Wonderware InBatch, 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.

“Baxter wanted to introduce the latest technology and determined that Wonderware System Platform provided a comprehensive solution that enabled the company to maintain a library of functional objects that could be reused in the future,” Bassem said.

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“In addition, Wonderware System Platform enabled us to simulate equipment behavior to encapsulate advanced functions that would enable Baxter to manage all system interactions on the production line. This allowed us to view the operation of equipment to ensure all functions worked smoothly together.”

Wonderware InBatch 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 Wonderware System Platform and Baxter’s existing MES systems.

“Other requirements including database interoperability, smart calculations and production report generation were easily managed by Wonderware System Platform,” Bassem said. “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.”

Using the powerful toolkit provided by Wonderware System Platform has enabled the BiiON engineers to create roughly 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.

“For more than a decade Baxter, BiiON and Wonderware have worked collaboratively to implement new technologies designed to improve Baxter’s overall manufacturing processes,” Bassem said. “To ensure the success of such a huge project as this one required close collaboration between the customer, the software and hardware providers as well as the systems integrator. By establishing a comprehensive automation framework based on Wonderware applications, Baxter is now equipped with a flexible system required for its future growth strategies.”

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.