ABB's Facility Automation Solution (FAS) unites GxP and non-GxP Automation in Pharmaceutical Plant

ABB's Facility Automation Solution (FAS) achieves three crucial objectives of pharmaceutical companies: controlling both GxP and non-GxP areas; integrating both legacy and future systems; and combining regulatory compliance with both operational efficiency and low cost.

Client:	**Confidential Pharmaceutical Company**
Location:	**United States**
Scope of Work:	**Unified automation, monitoring, and control of plant utilities and environment for GxP and non-GxP areas**

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In the Life Sciences industry, ABB is known for our strength in validation, engineering, and process control—as Industrial IT FAS demonstrates. FAS controls and monitors environmental conditions during and after the manufacture of a particular batch, recording operator actions that might affect those conditions. The data is consolidated from multiple sources and goes to a secure GxP repository, without the need for re-qualification. Then FAS creates reports that meet both operational and compliance requirements.

Background:

Like many of its competitors, this leading pharmaceutical company has grown with each success in pharmaceutical therapies, vaccines, and oncology products. Its over-the-counter medicines, oral care products, and nutritional drinks are all market leaders. As the product line expands, new and upgraded manufacturing facilities are needed. At every stage, the company is committed to quality products and regulatory compliance. It's also committed to maintaining production goals and profitability.

Over the years, different areas in the company's U.S. sterile manufacturing facility have been automated with different, independent, and sometimes incompatible systems. These "islands of automation" were making it difficult to maintain a uniform standard of good pharmaceutical practice (GxP).

Solution:

For this customer, ABB's Facility Automation Solution has now eliminated the islands of automation in both GxP and non-GxP areas. The system:

- monitors and controls the plant utilities (such as chillers, cooling towers, and condensers); air handling units (AHU) and their associated humidifiers, coolers, and damper controls; and heating, ventilation, and air conditioning (HVAC)
- maintains the physical environment of the manufacturing area in a known state
- has the ability to integrate subsystems such as access security and energy management
- standardizes the interfaces to legacy processing equipment
- provides trending, alarming, and exception handling
- combines key environmental data into the batch production record
- offers a secure data repository that is 21 CFR Part 11 compliant; access is based on a user ID and encrypted password, with individual assignment of specific access rights
- provides higher quality data, enabling optimization of the manufacturing operations
- allows operators to enter comments
- creates combined, pre-defined compliance and operational reports; and permits the creation of ad hoc reports by authorized users
- performs self-diagnostics

Built on a System 800xA platform, FAS creates a single user and engineering environment across the entire facility, improving both efficiency and security. Because FAS is part of ABB's Industrial IT line of solutions, it is validated, expandable, and flexible. It integrates with legacy systems, allowing the pharmaceutical company to build on past investments; it's easily expandable to other process automation applications within the facility; and it's a secure automation platform on which to base future process automation enhancements.

"ABB's Facility Automation Solution provides me with what I need at the price I want to pay," says the engineering manager of the pharmaceutical operations complex. "I want to be able to see two, three, or four years down the road where I want to be. ABB products have given me the ability to reach that vision. I'm looking for certain standards," he adds, "and ABB is following those standards."

Benefits

- Elimination of islands of automation
- Control over both GxP and non-GxP areas of the facility using one system
- Improved and secure access to data from a variety of sources
- Compliance with the most recent regulatory requirements, and the flexibility to comply with future requirements

The FAS for this facility includes eleven active workstations, engineering, batch and Information Manager Server, built-in redundancy (including a redundant Historian), and software for five AC800M controllers, with more than 950 I/O points. FAS incorporates Industrial IT System 800xA technology. System 800xA presents plant data and components as easily configured software objects containing a range of information that's instantly recognized by plant-wide information networks. With System 800xA, FAS delivers a continuous savings in operator efficiency, application development, validation, and management of the automation system.

ABB has also supplied project management, i.e., engineering services for the design, build, test, installation, and validation of the GMP applications, as well as customer training. In line with ABB's philosophy of life-cycle support for our products, an ABB Engineering Center is located less than 15 miles from the customer's site.

ABB's Facility Automation Solution is allowing this leading pharmaceutical company to attain strict regulatory compliance and control over the production environment, without jeopardizing product quality or production planning. Because it permits easy upgrading and modular expansion, FAS will meet the needs of the company far into the future.

For more information on solving your life sciences regulatory compliance and control system issues, visit us at www.abb.com/lifesciences.

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