Life Sciences

Wonderware®

Baxter S.A.

Lessines, Belgium

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

- 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

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

Industry: Life Sciences

"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, CEO
BiiON (Baxter System Integrator)

Fujirebio Diagnostics, Inc.

Malvern, Pennsylvania

Goals

- To replace an existing paper-based GMP record system and manual process with an electronic monitoring system

Challenges

- A significant amount of time is spent each day manually reviewing reports
- The existing paper-based system was time consuming and vulnerable to reporting errors
- A new system must enable the company to remain in compliance with federal regulation

Results

- The company's Electronic Initiative helps produce 75 million tests that are distributed throughout the world
- The solution is completely paperless and provides electronic record collection with electronic signatures while maintaining 21 CFR compliance and ISO 9001 and 13485 certification
- The equipment monitoring system saves about 1,100 man hours per year
- The tasks related to manually logging equipment parameters and reviewing paper logs and charts is eliminated and has reduced data reviewing time from 15+ hours to just minutes
- Electronic monitoring saves 2/3 of time, or about 10 hours per month in quality assurance

Industry: Life Sciences

"The largest benefit of the equipment monitoring system is that we are logging automatically now rather than manually, so it's saving us about 1,100 man hours per year."

Josh Zimmer,
Quality Engineer
Fujirebio Diagnostics, Inc

Rottendorf Pharma GmbH

Germany

Goals

- Monitoring of production, laboratory and storage conditions throughout the enterprise
- Proper collection and long-term preservation of monitoring and process data
- Visualization and distribution of alarms and notifications
- Flexible data analysis and standard reporting
- FDA-compliant storage of GMP-relevant parameters

Challenges

- Monitor environmental conditions through a multi-stage alarm system
- Compliance with legal requirements and regulations
- Qualified system environment/application
- GMP-compliant user administration
- High product safety combined with maximum production flexibility

Results

- Collection, analysis and storage of GMP- critical parameters - including differential pressure, temperature e relative humidity - in production, laboratory and storage areas.
- System-generated users alarms in case of specification violation, including escalation mechanisms

Industry: Life Sciences

“Individual GMP-compliant automated systems bring benefits especially in situations where consistently high quality and flawless monitoring of manufacturing conditions are required. ”

Hironobu Hirakawa
Development Manager

Xcellerex

Marlborough, Massachusetts

Goals

- Address the growing demands in the biomedical market space for more effective biopharmaceutical manufacturing processes
- Develop a solution that would define a model for improving how biopharmaceuticals, vaccines and other therapeutics are developed, manufactured and commercialized

Challenges

- Integrating complex technology with ultra-high levels of functionality was considered the greatest challenge in creating a biomanufacturing platform that employs a single-use technology, controlled environment modules, process automation and electronic batch records

Results

- Xcellerex's FlexFactory achieves significant cost savings, including a capital investment reduction that can exceed 60 percent
- Reduces deployment time from three to five years to 12 to 18 months
- The solution achieves an overall reduction in development time of nearly 60 percent, with an estimated 80 percent saving in rework time

Industry: Life Sciences

"We've been able to reduce deployment time from 3-5 years to an amazing 12-18 months. This results in huge implementation savings and the ability to begin producing high value product 2 to 4 years sooner than traditional technology."

John A. Chickosky
Chief Commercial Officer and President, Biosystems

Wonderware Finland & Baltics

HELSINKI
tel. +358 9 540 4940
info@klinkmann.fi

RĪGA
tel. +371 6738 1617
info@wonderware.lv

VILNIUS
tel. +370 5 215 1646
info@wonderware.lt

TALLINN
tel. +372 668 4500
info@wonderware.ee