GE Intelligent Platforms



Pfizer Newbridge

Driving business value through integrated automation

RESULTS

- 25% reduction in expansion lead-time
- 23% reduction in resources
- 20% reduction in Investigation Time
- Reduced time to maintain
- 'Plug & Play' flexibility
- Increased scalability
- Automated "OEE for Batch"

"We are now working with GE to really understand how to gain the most value from all of our data. At the early stages we were data rich but knowledge poor. Understanding all of the data collected and how we can use it, both at the Enterprise and Quality layer, is enhancing our knowledge base and demonstrating ROI for our automation and engineering efforts"

Claire Comerford, MHT PPU Director

Pfizer Newbridge created outstanding business value by moving away from islands of automation using an integrated automation strategy from GE

Pfizer Newbridge pharmaceutical products treat and help to prevent some of the world's most prevalent health issues. The product portfolio includes innovative treatments across a wide range of therapeutic areas.

The Newbridge facility currently produces 80 different product formulations packaged in approximately 650 different pack-to-market presentations, covering:

- Hormone Replacement
- Oral Contraceptives
- Central Nervous System

The site was established in 1992 and covers 120 acres at Newbridge, County Kildare, Ireland. As an organization, Pfizer is committed to applying science and its global resources to improve health and well-being at every stage of life. To support this commitment to delivering products of exceptional quality, the engineering team at Newbridge has put in place a world-class Batch automation scheme from GE Intelligent Platforms across both of its new facilities for MHTs (Menopausal Health Therapy) and OCs (Oral Contraceptives).



The Technical Approach

At inception, the project team made a fundamental decision to provide capacity in the project for up-front, low level technical customization. This was done in order to drive future high-level flexibility. The team invested in strong programmable logic controller (PLC) and supervisory control and data acquisition (SCADA) standards as a guiding principle, which provided a structure that proved, during the course of the project, to give greater flexibility and agility.

These PLC and SCADA standards are closely coupled to truly realize the power of the Batch Engine used to control production. The team selected GE's Proficy^{*} iFIX HMI/SCADA and Proficy Batch for batch execution as they deemed it the best-in-class technology platform.

Another guiding principle was centralized, single point recipe management and execution, across all unit classes. This approach provides the ability to create, store and maintain control recipes within a controlled environment.

"Having all of our Master Recipes in one location, and the use of class-based recipes, reduces my time in maintaining and changing recipes and cuts down greatly on our paper work," said Eoin McMahon, Automation Engineer, MHT Pfizer Newbridge. "Our class-based approach has also led to greater repeatability."

The Technical Journey

"During the design and project phases every skid was tested off site and brought to a fully functioning state using localized iFIX SCADA and Batch recipes at our vendor's facilities," said Alan Shefflin, Automation Site Lead. "Once on site here at Newbridge, thanks to the 'Plug and Play' flexibility, it was connected to our central Batch and SCADA systems and commissioning could begin. Due to the level of activity and number of resources involved during this phase, each vendor team utilized a fully functioning and secured development node local to their process cell. This allowed speedy validation with teams working side by side but without cross over."

Once this project phase was complete the Thick clients were obsolete and moved over to a centralized, thin client, architecture within the control room. One Proficy Batch and iFIX engineering thick client was kept for automation and maintenance activities.

This now provides for:

- Creation, monitoring, and execution of the control recipes
- Standardization of graphics across multiple vendors and a single source of alarm management while minimizing customization
- Unexpected process excursions alarmed for operator response.
- Reduction in Paper Method through EBR
- Real time monitoring of exceptions occurring during the manufacturing process.

Support

The site also understood the benefit of having GE on the ground. From early on in the project phase Pfizer involved GE Field Service and contracted an embedded GE engineer to work full time with the automation team.

This allowed issues to be addressed on site as they arose and now this relationship is helping Pfizer define its automation vision as they start to optimize and extract real value from the automation layer.

Secure data

The site puts a very high value on the data collected. This is held in a centralized data historian system (DHS) to 21CFR11 standards using GE's Proficy Historian. The site DHS incorporates Proficy iFIX alarms collected through the iFIX Alarm Open Database Connectivity (ODBC) service, Batch event data archived into the Batch Journals and Process data is collected in Proficy Historian. This provides standard historical and real-time trending independent of equipment type or data source, which enables production staff to take insightful decisions across apparently disparate operations. The information is displayed and made available for analysis through one central Data Historian Server for all functions.

"By up-skilling our operations team through automation 'on the job' training they were able to interact effectively with all technical systems for day-to-day operation and to aid troubleshooting," said Michael Howell, Operations Lead, MHT Operations, Pfizer Newbridge, Ireland. "This combined with the centralized control room has great benefit."

Balancing people and automation

The old school, heavy industry philosophy of 'Hand-Mode' even found its way to a high tech facility like Newbridge. The engineering team understood the importance of allowing controlled, secure and safe manual control of equipment when required either for maintenance functions.

To support this, the manufacturing control system is able to perform direct control of local controllers if required through standard phase and control module level manual modes. This can be carried out from any one of 60 Proficy iFIX thin clients across the floor deployed with Citrix Technology.

Building Management

To support environmental conditions for containment alongside all 'non GMP' parts of the plant the Building Management System (BMS) was divided into two portions: a non-qualified BMS; and a qualified BMS. This system was designed to

• Support containment to protect product quality and reduce gowning requirements

• Follow site-wide standards, allowing alignment with legacy systems where required but with 'value-add' integration where appropriate, e.g. Process Trend Data

Manufacturing Execution

To gain the most value from the highly integrated automation system, a manufacturing execution system (MES) solution was incorporated into the plant design to

- Provide functionality through Electronic Batch Records (EBR) to guide the production in conformance to the batch record
- Ensure acknowledgement and commenting of Level 1, Good Manufacturing Practice (GMP) alarms during batch processing

Across both the MHT and OC facility a Self-Guided Vehicles (SGV) system was installed, including standard Intermediate Bulk Container (IBC) sizes across all units to reduce human interaction for material handling. This system interacts with all equipment through the Batch Execution system. enabling the process equipment to automatically request a load or unload during a recipe cycle.

With a standardized PLC footprint along with one SCADA solution a centralized software management system was used. This is responsible for maintaining oversight and management of the software versions of applications within the control system. Seeing the value in one storage location and moving away from 'fire-safe' syndrome has lead the automation team to expand this system to cover all automation related design documents.

"Because access control is managed using the site Active Directory and process data is managed automatically in the integrated automation environment, more time is available to the automation engineer for plant optimization," said Eoin McMahon.

Learning

One of the biggest lessons learned was in the area of PLC and phase logic. Batch Execution offers excellent integration using either full 'PLI phases' or Direct Phases where required. Although Direct Phases offer a simplified and flexible phase/equipment interface they were found more suitable for smaller systems that do not require a PLI. For greater future flexibility, where a higher degree of integration is required, the site will now use full PLI Phases.

This approach of low-level customization offering high-level flexibility was applied to all systems from PLC and SCADA through to Batch.

"The standards we have invested in, and evolved, can now be used to scale up our existing facility," said Fergal McTiernan, Engineering Manager, Pfizer Newbridge. "We have an estimated 80% additional capacity and I estimate a 25% reduction in the FAT-IQ stage of the project lifecycle thanks to the flexibility of an integrated batch system like this."

The future

"We are now looking to take the next steps with our N-SmarT (Newbridge System of Manageable Automated Results for TPM) program and are piloting an 'Overall Equipment Effectiveness (OEE) for Batch' on our coater using Proficy Plant Applications in partnership with GE through their SmartStart program," said Paul Conroy, MHT OE Lead. "The largest challenge here was breaking down a complicated batch process like coating into its discrete components and then applying standard OEE rules. GE was able to provide real insight with this. We are now reviewing further OEE requirements site wide and are also seeing the value in process understanding through the Batch Analysis reports within Proficy Plant Applications."



A number of site-wide projects including the PWCAMS (Plant Wide Critical Alarm Management System) project are also being reviewed to see if a link to PA could be made and the information collected in PWCAMS could be used to trigger Work Instructions into SAP. The site is currently planning to pilot Proficy Maintenance Gateway to prove this concept.

"We also aim to leverage our investment made with GE and Plant Application to aid in the site-wide water reduction program," concluded Michael Howell.



The 'Instrument to Enterprise' Vision

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