



Life Sciences / Pharmaceutical Successes

Global References & Case Studies

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Overcoming life sciences and pharmaceutical industry challenges

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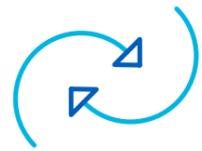
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Outcomes



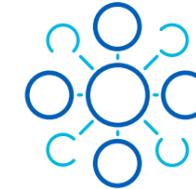
Increase agility

Manage your batch execution for greater agility and reduced costs. You can streamline end-to-end operations, ensure product quality, and drive high-volume production, even when switching products between batches is a requirement.



Adhere to regulations

Complying with stringent regulations is a must. Support your traceability, data management, reporting, and continuous improvement needs with proven, modernized technologies. Furthermore, enforce Standard Operating Procedures by guiding operators through the right steps and tracking performance.



Optimize operations

By integrating and analyzing the data being generated on production lines, improvements can be made across plants including on batch variation, ingredient consumption, quality costs, waste, and management of abnormal situations. Optimizing also alleviates knowledge gaps between experienced and new operators.



Speed time to market

Improve your ability to compete against generics, penetrate new markets, and leverage existing products prior to patent expiration with digital transformation. You can improve local production operations while meeting global requirements. With a connected enterprise, you can accelerate time to market and boost competitiveness.



Improve quality and output

By monitoring your equipment and production lines with industrial applications, life sciences and pharmaceutical manufacturers can shift from schedule-based maintenance practices to more condition-based or preventative maintenance practices. This helps eliminate vulnerabilities in the production lines – improving both product quality and output.



Transform data management

Digitize historically paper-driven processes and records, moving to electronic SOPs, specifications, BOMs, batch records (EBR), maintenance logs, and more. Additionally, a plant- or enterprise-wide data historian increases performance, boosts data integrity, reduces costs, and provides a foundation for IoT continuous improvement.



Alcon Puts Strong Focus on Validation for the Production of Eye-Care Products

Significantly Faster Response Times with Historian and High Performance Trend Analysis



Originally founded in 1947 by pharmacists Alexander and Conner, Alcon has grown to a world-wide pharmaceutical vision-care manufacturing and research company with over 10,000 employees. By expanding to multi-national production facilities and through continuous investments in research and development, Alcon has established a leadership in the eyecare field.

Alcon Belgium provides production facilities for specialized eyecare products. The production is organized into four divisions, each with very strict requirements for the automation layer. The pharmaceutical industry has always been subject to strict regulations. Production of medication and health care products must take place under the most severe registration rules, in order to comply with the regulating authorities. Following the trend for more automated production processes, the FDA has formulated an electronic definition of process tracking in the form of 21 CFR Part 11.

What does 21 CFR Part 11 mean in practice?

In an attempt to structure and guide line the continuous replacement of the current paper work flow in production processes, the FDA has formulated a set of definitions for electronic signatures and work-in-instructions. Working in a validated production environment basically means enforced security in combination with an extended audit trail. Every single change to the production system needs to be captured, recorded and archived into a closed and secured database.

“With the Proficy Historian product the response times are 20 to 30 times faster than with the traditional trending tools”

— Dirk Steeman, Automation Manager,
Alcon Couvreur, Belgium

How to apply to these rules

Implementation of a validated electronic tracking system requires a structured approach from the bottom up, Alcon has adopted an object oriented control layer approach, starting with the organization of standard building blocks in the PLC. Each sensor value goes through a number of standard function-blocks to calibrate, check alarm boundaries and calculate before it reaches its final value. Set points and calibration can only be changed by authorized personnel and are checked continuously within the PLC.

Every non-conformity and deviation is automatically reported through the standard SCADA system iFIX from GE Digital to a central database from which daily reporting takes place. Authorization is enforced through out the entire system using the seamless integration-of security within iFIX and Microsoft Windows®.

SUMMARY

COMPANY

Alcon Couvreur, Belgium

SOLUTIONS

- Production Management
- Process Visualization
 - Process Validation
 - Plant Information

PRODUCTS

- iFIX
- Proficy Historian

BENEFITS

- High performance trend analysis
- Integrated security complement to 21 CFR part 11
- Low cost plant Historian
- Secure base for reporting



Validated Applications

From a hardware point-of-view, the network infrastructure is physically split into an administrative and a production network. The production-network itself is split into a part for validated applications and a part for non-validated applications. The validated applications deal with the continuous monitoring of the environmental production room condition (temperature, pressure, humidity, etc) and manufacturing equipment status. Within the validated part no changes can be applied without the explicit authorization of the internal validation department, again enforced by the system. The use of standard building blocks both structures and simplifies the validation process.

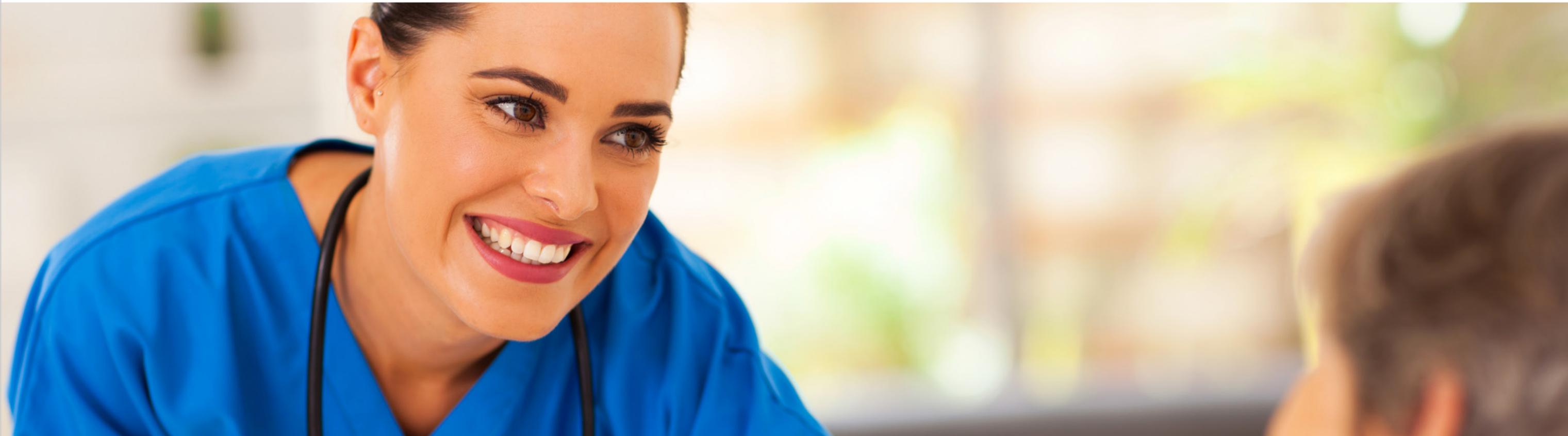
High Performance Data Historian

In their continuous search for process improvements, Alcon has adopted the Proficy Historian product. With a built-in 21-CFR-Part 11 compliancy the product is able to capture historical process values and store these into central archives. Historical values are often required for trend analysis and reporting by both the QA department and production personnel. The main reason for Alcon to purchase Proficy Historian was its tremendous increase in performance over the existing trending tools. Response times have increased enormously, while the impact on the existing installation is kept to a minimum. The sophisticated compacting functionality minimizes the required disk-space, which means for Alcon a disk-space requirement of only 0.5 MB for the recording of 30,000 tags per day.





Minimal downtime saves Coloplast vital resources



At Coloplast, the innovative and world-renowned provider of healthcare products and services, the need for an efficient packaging flow for its wide range of wound care products is ever increasing.

By installing new Proficy OEE software on all its packaging machines and working with GE Digital partner Novotek, Coloplast is gaining unrivalled insight into the various causes of operational downtime. Simultaneously, automated production data analysis can speed up downtime diagnosis, providing production managers with more knowledge of what action to take to keep the vital packaging process up and running.

"Tried-and-true technology from Novotek has given us the flexibility and transparency we need to maintain superior quality in our dynamic packaging process."

— Birger Andersen, Project Manager, Coloplast, Denmark



Fast Response Times

As packaging is at the end of a highly specialized production process, flexibility is vital if Coloplast's round-the-clock packaging operations are to keep running smoothly. Naturally, when short-notice shifts and unscheduled production halts occur during packaging, operators must respond immediately. With Proficy software automatically surveying every packaging step on every machine, problems can be identified and solved when they first arise, cutting response times to a bare minimum.

High Transparency

A detailed overview of several hundred downtime causes provides Coloplast with a fully transparent packaging process. Both scheduled and unscheduled stops are registered and analyzed, and numerous analytic options are presented. Management can then quickly isolate variables, detect downtime patterns and draw detailed downtime profiles for each machine and packaging step.

Solutions

- Production Management
- Global downtime analysis
- Plant information

Products:

- Proficy Historian
- Proficy Plant Application—Efficiency
- iFIX HMI/SCADA

Benefits

- Increased line and machine efficiency
- Fast response times
- High transparency
- Realistic predictions
- Web-based reporting

Realistic Prediction

With the detailed historic data from each machine, combined with the in-depth downtime knowledge, management can also accurately predict future packaging capabilities. The Proficy data computation forecasts are accurate right down to number of units on a day-to-day and individual machine basis, so manpower is allocated most effectively and the budgeting process is enhanced. Predictions are no longer based on feelings and hunches but on facts and indisputable data.

Common Standards

By introducing the Proficy OEE machine downtime analysis to several packaging processes, Coloplast has reaped the benefits of having a single knowledge base. Comparisons of packaging quality between product lines and divisions reveal the causality needed to optimize every step and component of the packaging process, on single machines, at product-type level and on a company-wide scale.

More User-Friendly

Coloplast wanted to provide its production crew with easy to-understand functionality, so a tailor-made front-end user interface was integrated into the iFIX SCADA package. By way of a logic and intuitive control environment, operators know exactly where and why production has stopped. And as the touch-screen user interface resembles the familiar manual touch-button environment, operators can instantly report and correct OEE problems.



“Before we installed Proficy OEE software, it could take two weeks to manually pinpoint downtime problems from perhaps ten known causes. Today, we have a clear knowledge of over 200 possible causes from one day to the next.”

— Birger Andersen, Project Manager
Coloplast, Wound Care Div.

GE Healthcare Life Sciences - Austria Digitizes Environmental Monitoring



GE Healthcare Digitizes Environmental Monitoring at Austria Sites

GE Healthcare Life Sciences recently boosted its capacity for producing a critical material used to make life-changing therapies. The tenfold annual capacity increase for powdered cell culture media at its Pasching, Austria facility strengthens supply to biopharmaceutical companies in Europe. These companies produce biologics, including vaccines and monoclonal antibodies to treat cancer, now the world's fastest-growing class of medicines.

The Pasching expansion is part of a \$17 million USD investment to create state-of-the-art facilities for cell culture media production. In addition to increasing capacity at GE's Pasching and Logan, Utah sites, the investment fuels updates to modernize and digitize production for continuous improvement. Consistent with these goals, the new Pasching production suite also has a new digital solution that streamlines environmental monitoring.

Products

- CIMPLICITY HMI/SCADA
- Proficy Historian



Challenges

Digital solutions support continuous improvements

Manufacturing cell culture media, the nutrients for cells that are used to produce biopharmaceuticals, is a complex process. Different formulations enriched with amino acids, vitamins, fatty acids, and lipids have been created to optimize the growth of a wide range of cell types. The production process, including the environment, must be precise to minimize variations that could affect cell growth in the biologic manufacturing process.

With continuous improvement in mind, the Pasching team aimed at boosting visibility of the environmental parameters (temperature, pressure, humidity, etc.) in the production area. The team wanted real-time notifications on multiple devices, allowing maintenance or engineering staff to respond even more quickly to changing parameters during the production run. It also wanted to improve the ability to identify trends and analyze data proactively. During the planning phase for the expansion, the team broadened the project scope to also include the implementation of a new monitoring system fitting these requirements.

“At GE Healthcare, we continuously aim at improving the quality of finished goods. As a life science company, we have very strict requirements on each supplier we choose. That’s why only the high-quality technologies can be used in our initiatives,” says Florian Zocher, GE Healthcare Pasching Manufacturing Program Manager. “And then, when we started our production extension, the natural choice was GE Digital, as a reliable software editor and solution provider. It was not the first project with GE Digital and after this huge success it won’t be the last”.



Solution

HMI/SCADA visualization across the plant floors

GE Digital partnered with ProKSE GmbH (Germany) to implement CIMPLICITY to allow Pasching staff to react even more quickly to changing parameters before production was completed.

“We needed an experienced partner with deep knowledge, who can provide GE-like level of services—therefore we have selected ProKSE,” said Luca Galiotto, GE Digital project lead.

“CIMPLICITY, a core component of the solution, allows us to fulfill the requirements using maximum standard functionality of the software,” indicated Maria Dudorova, ProKSE GmbH technical lead. *“This means reduced TCO for the end customer.”*

CIMPLICITY’s situational awareness technology, combined with an advanced notification system (via email and SMS), allows maintenance or shift leaders to receive notifications quickly. These alerts indicate the exact location of the environmental parameter in question and identify the cause. The notifications can also be received on multiple devices, including displays on the shop floor, desktop computers, and mobile devices. So, the right information is delivered to the right people at the right time.

Proficy Historian from GE Digital also enabled the quality department to visualize trends and then create the appropriate analysis. To provide greater visibility, plant floor data was collected from PLCs and reliably stored in the Historian server—preventing data loss in case of disconnection.

“The security aspects such as electrical signature, single sign on and audit trail were very important for us because we must follow the industry regulations – 21 CFR, for example,” says Stefan Seyerl, GE Healthcare Pasching Digitalization Specialist. *“Since being involved in the project, I am contented not only with how the proposed solution fits our requirements, but with how GE Digital and ProKSE worked for us.”*

To provide this high level of visibility, plant floor data was collected from PLCs and stored in Historian. The built-in features of redundant collectors, used for this aim, prevent data loss in case of disconnection between the PLC and the plant Historian server.

Results

Flexible implementation and reduced cost

With GE Digital’s industrial applications, the Pasching facility personnel now have a powerful tool at their fingertips. They can select one parameter on a specific display to see and analyze the data in real time. This not only saves time and cost, but reduces waste and rework as well. The solution also allows Pasching staff to:

- Respond even faster by receiving early notifications
- Continuously improve trend identification and data analysis
- Reduce costs by pinpointing parameters to analyze

In the future, the team at the Pasching facility is planning not only to implement this solution in new areas, but also to update existing environments.



Genzyme speeds data collection and production reports



Genzyme Speeds Data Collection and Production Reports

Genzyme has been a fully owned subsidiary of Sanofi. As a subsidiary of Sanofi, Genzyme has a presence in approximately 65 countries, including 17 manufacturing facilities and nine genetic-testing laboratories. Its products are also sold in 90 countries.

Products

- iFIX HMI/SCADA
- Proficy Historian
- Proficy Workflow



Challenges

Quality, Maintenance and Performance Reports

- Server operations were slow and sometimes didn't complete while generating quality, maintenance and performance reports on long production runs.
- Secure and speed up Genzyme's data collection and production reports.

Solutions

New Plant-Wide Historian Added to Proven Automation Solution

In addition to its long-time use of iFIX HMI/SCADA from GE Digital, Genzyme rolled out an enhanced OT architecture, adding a new Proficy Historian module from GE Digital to two existing servers, archiving a total of over 20,000 tags.

Additionally, the team upgraded the existing Proficy Historian of 10,000 tags, providing Genzyme with advanced insights into their collected production data.

Furthermore, advanced adoption of GE Digital's Acceleration Plan for Support and Maintenance Services ensures Genzyme's production operates at its highest efficiency.

Architecture

Proficy Historian for Data Management Enhances iFIX HMI/SCADA Monitoring and Control

- Collect, archive and visualize production reports with no impact on the performance of the existing installation
- Automatic daily refresh of the data from the new Proficy Historian server and manual clean-up if upon request
- Integrate data to ensure information is traced, secure-by-design, accessible, and not lost
- Reduce costs by optimizing data storage cost

Results

Lower Data Storage Costs with Plant-Wide Historian

- Achieve fast time to value with simple installation and easy-to-use Web clients with integrated tag search and drag-and-drop features
- Supports high availability with server redundancy
- Leverage continuous and highly scalable data read-and-write functionality
- Reduce storage costs
- Save time and costs with seamless ingestion to HDFS, adding time-series data to your big data analytics
- Take advantage of the time-saving dashboard, whereby critical data finds you
- Real-time / Faster insights enables viewing data within trends and context of the plant data model to determine root causes and turn the data into actionable information.
- "Single source of truth" and real-time/faster visibility into process data and trending

JHP Pharmaceuticals

(now part of Par Pharmaceutical)

Paperless Manufacturing Enables Repeatable Production



JHP Pharmaceuticals

Paperless Manufacturing Enables Repeatable Production

Pharmaceutical companies often manufacture more documentation than product. With Proficy Workflow, JHP, now part of Par Pharmaceutical, reduced paper consumption and operator errors by digitizing their standard operating procedures and creating an electronic master batch record.

Data is automatically populated into the forms from the plant SCADA system. Operators use E-Signature to sign off on every step, but the real value is a replicable solution that can be reused across the site with minimal retest.

“Significant opportunities exist for improving pharmaceutical development, manufacturing, and quality assurance through innovation in product and process development”

— **Mary Grow, VP ET & Business Processes, JHP Pharmaceuticals (now part of Par Pharmaceutical)**



Products

- Proficy Workflow
- iFIX HMI/SCADA
- Proficy Plant Applications
- Proficy Historian

Results

- Reduced paper consumption
- Reduced operator errors
- Improved product safety
- Real-time process data for decision making
- Reusable solution that can be applied across many different lines without full retest



Lek Pharmaceuticals leverages solution to control and monitor environmental conditions

"A synergy of two requirements—high reliability and rich functionality—was achieved by using the [GE Digital] industrial equipment and appropriate control algorithms implemented at different levels."

**Saša Sokolić, Ph.D., Member of the Management Board,
responsible for Sales and Marketing in Metronik**

Results

- Solution for HVAC control and supervision was developed, tested, and commissioned on-site within eight months
- Production flexibility increase due to automatic process adaptation in case of new production demands, or modification of clean-room functionalities
- Synergy of two complex requirements, high reliability and rich functionality, achieved by using highly reliable industrial equipment and appropriate control algorithms implemented at different levels
- Configurable PC application fulfills all regulatory requirements, as well as recommendations, for the pharmaceutical industry
- Solution provides a complete overview of energy use, and consequently, operational costs, assisting management in analyzing and optimizing energy usage to reduce operational costs

Lek, a Sandoz Company, uses GE Digital's iFIX-based solution to control and monitor environmental conditions and energy usage

Founded in 1946, Lek is a part of Sandoz, one of the world's leading generic pharmaceuticals manufacturers. It operates as a global development center for products and technologies, as well as a global manufacturing center for active pharmaceutical ingredients and medicines. The company is also a competence center for vertically-integrated product development, including generic medicines along with pharmaceutical, and biotechnological active substances and anti-infectives, as well as development and manufacturing of biopharmaceutical products. It is the main supply center for the CEE, SEE, and CIS markets.

The OTO2 production plant is one of Lek's largest production sites in Slovenia, with specialized high-technology process equipment for producing generic drugs. Key product groups include antibiotics, treatments for central nervous system disorders, gastrointestinal medicines, cardiovascular treatments, and hormone therapies (for example AMOKSIKLAV, IBUPROFEN, KETONAL, LEKADOL, etc.).

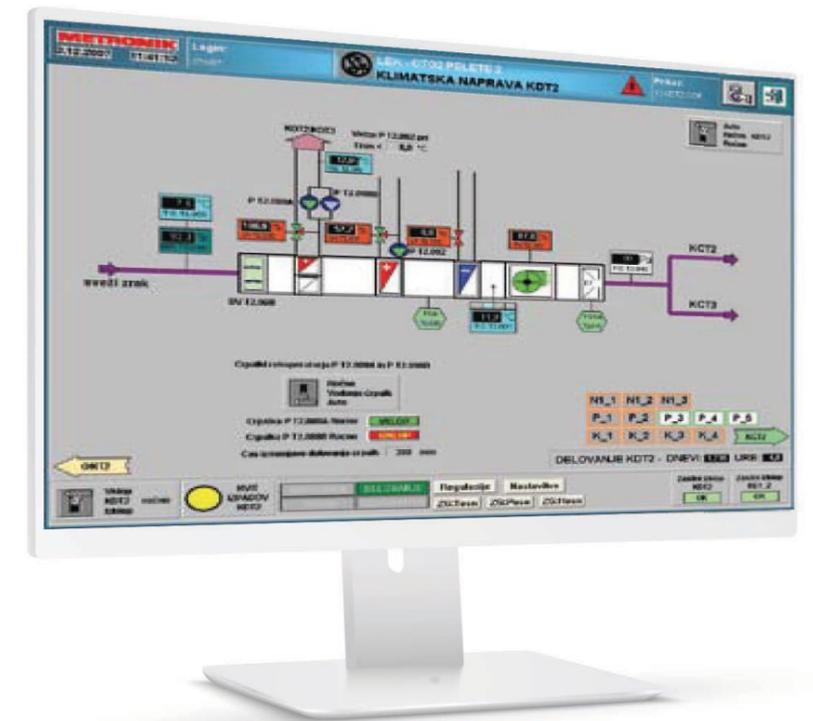
In recent years, Lek has been expanding, and has modernized its production capacity and strengthened its position inside the Sandoz group. Plant OTO2 follows high standards of sterility, safety, and quality to meet strict FDA approvals.

The production of pharmaceutical products requires specialized and controlled environments, where sterile conditions have to be maintained. Therefore, heating, ventilation, and air-conditioning systems (HVAC) are necessary for controlling these environments. A control system for HVAC is a critical factor, which affects the reliability of analysis results, experiments, and production systems. One of its most critical tasks is to prevent outside air from entering the facility.

Therefore, Lek required a validated and highly reliable building management system/environmental monitoring system (BMS/EMS) solution for HVAC control and supervision to provide precise, critical control of temperature, humidity levels, and airflow patterns at the OTO2 production site. The solution had to provide complete remote control of all HVAC systems, automatic adjustment of process parameters according to production demands, alarm management, efficient visualization, and trending, together with process data archiving and reporting.

Introducing the complete BMS/EMS solution for HVAC, Lek wanted to provide fully controlled conditions in OTO2 to enable effective production and energy management, increase the level of quality control, as well as increase flexibility and production adaptation to new demands.

Since plant and all production facilities have been designed according to GAMP¹ recommendations, the company's HVAC solution had to meet respective pharmaceutical regulatory requirements and recommendations.



HVAC system visualization



Trends of the process variables: temperatures (fresh air temperature, temperature behind refrigerator, etc.) and valves

Integrated control provided

Lek turned to GE Digital's solutions provider Metronik, a leading systems integrator for process control and automation for the pharmaceutical industry in the Eastern European region. Formed in 1990, Metronik has 17 years of experience providing more than 1,000 air-conditioning units automated, commissioned, and validated on more than 50 different production sites. The company, headquartered in Ljubljana, Slovenia, with offices in Zagreb, Croatia, Belgrade, Serbia, and Sofia, Bulgaria, employs more than 50 engineers for its project teams.

Metronik delivered a flexible, high-powered, integrated BMS/EMS solution for HVAC system in Lek's production plant OTO2 based on proven industrial equipment, such as GE PLCs (now part of Emerson) and iFIX from GE Digital to assure accurate and reliable control.

The GE PLCs come from a family of controllers, I/O systems and specialty modules designed to meet the demand for versatile, industrial solutions—helping businesses gain a sustainable advantage. With its single overall control architecture, this controller has been the PLC of record in more than 200,000 applications, such as high-speed packaging, material handling, and complex motion control.

With the power of leading technologies and patented techniques, GE Digital's iFIX is the ultimate tool for visualization, automation, and in delivering analytics to drive the lowest possible total cost of ownership. The software provides a comprehensive monitoring, analysis, control, and distribution of their plant-wide data. With applications in industries including pharmaceuticals, biotech, consumer packaged goods, food and beverage, oil and gas, water, waste water, power, and others, iFIX is the right HMI or SCADA solution for any automation environment.

"The environmental conditions have a strong impact on product quality in OTO2. Therefore, we had to establish a system to adequately control these environmental conditions," said Aleš Dolenc, Lek, Technologist Energetics Department. *"Together with Metronik, an integrated EMS/BMS solution for HVAC was deployed for the production plant. It enables flexibility of the production process, as well as more consistent and controlled HVAC system operation and maintenance, while eliminating the need for paper records."*

The main task of the Metronik solution is to provide precise control over environment parameters and conditions

in clean rooms by implementing control algorithms for temperature, humidity, and pressure. Changes in production demands are handled automatically by special control algorithms embedded in the PLC blocks. They are used to facilitate automatic control of output process values based on predefined set-up values, as well as provide a very fast response, and consequently, production adaptation in a very short time.

The solution enables rich graphical visualization of processes, conditions, and sensor values in real-time. All key parameters, such as alarm boundaries, PID loops, and production parameters can be accessed through SCADA. Power-users have the option to define two-level alarm settings for GMP (Good Manufacturing Practice)² and non-GMP parameters. Two modules running in real-time process data collection and an archiving module are incorporated into the solution, as well as a module for maintenance support, including fault diagnostics for all HVAC installation. All key data are stored into the Oracle relational database, and can be used for analysis and reporting.



Results achieved

The high-powered EMS/BMS solution combines the accurate control of heating, ventilation, and air-conditioning systems, as well as EMS solutions. It is used to monitor and control the critical and non-critical parameters coming from plant technologies.

“Our GMP compliant HVAC solution combines the environmental parameters monitoring functionalities (EMS), with the central building management system (BMS),” said Saša Sokolić, Ph.D., member of the management board responsible for sales and marketing in Metronik. *“Production flexibility increases have been realized due to automatic process adaptation in case of new production demands, or when the functionalities of existing clean rooms are changed.”*

Efficient visualization, alarming, and fault diagnostics for all HVAC equipment and installations in OTO2 provides plant personnel with efficient support for monitoring in real-time, and maintenance support in case of unacceptable or dangerous situations.

The validated Metronik solution fulfills the requirements for paperless HVAC system management, and complies with pharmaceutical regulations. And, the integrated BMS/EMS solution delivers lower TCO and maintenance of the complete HVAC system in OTO2.

“The Metronik engineering team has the knowledge and experience for implementing complex BMS/EMS building management systems for pharmaceutical production facilities,” said Lek’s Dolenc. *“Efficient visualization, alarm, and fault diagnostics for all HVAC equipment and installations provide efficient support for real-time monitoring and maintenance support.”*

“A synergy of two requirements—high reliability and rich functionality—was achieved by using the [GE Digital] industrial equipment and appropriate control algorithms implemented at different levels,” concluded Metronik’s Sokolić.

¹ GAMP (The Good Automated Manufacturing Practice - GAMP Guide for Validation of Automated Systems in Pharmaceutical Manufacture). Metronik system is designed, developed and commissioned according to GAMP 5 based project life cycle approach: User Requirement Specification, Quality and Project Planning, Specifications (Functional, Configuration and Design), Risk Assessment, Design Reviews, Software Production/Configuration, Test strategy and testing, User documentation and training, system support and maintenance operation, GMP relevance, 21 CFR Part 11 relevance.

² GMP is a term that is recognized worldwide for the control and management of manufacturing and quality control testing of foods, pharmaceutical products, and medical devices. Metronik system provides visualization and monitoring of the critical process data in compliance with good manufacturing practices—so called GMP critical parameters. CFR Part 11 relevance.





McNeil in Sweden chooses Proficy to increase OEE of its packaging lines



Improving OEE in the Nicorette® gum production plant in Sweden.

World Leading Product

At a location that has been manufacturing pharmaceuticals for over 90 years in Helsingborg in the south of Sweden, McNeil AB specializes in the manufacture of over-the-counter healthcare products. It is the only plant producing the world leading Nicorette family of nicotine replacement therapy products.

“We have been able to develop a customised solution, paying only for the elements we need.”

— **Annette Cederhag,**
Project manager Engineering Maintenance Utility, McNeil

Introduced in 1978, Nicorette gum provides the user with a source of pure nicotine while avoiding the harmful effects of tobacco smoke. By 2005, around 18 billion pieces of gum had been produced. Current production at Helsingborg is on a 24/7 basis of between 2 and 3 billion pieces per year, exported to around 80 countries worldwide.

Research and development takes place at the Helsingborg plant. In order to satisfy differing consumer demands, Nicorette has been developed into different formats which are also produced there. As examples, Nicorette Patch entered the market in 1991 to provide a continuous nicotine supply throughout the day; 1994 saw the introduction of Nicorette Nasal Spray for quick absorption of a nicotine dose; a Nicorette Inhaler was developed in 1996 which satisfies some users' demand to have their hands occupied; in 1998 Nicorette Microtab with a slow release profile for placement under the tongue was put on the market, and in 2004 a crisp coated, sweeter and softer mint gum was added to the Nicorette family, Nicorette Freshmint Gum.

OEE Under the Microscope

McNeil is continually looking at its working practices in order to improve the way it works. This comes under its 'Right First Time' concept. Small 'Right First Time' teams are looking at a number of the processes in Helsingborg to see if they can be improved, and the Overall Equipment Efficiency (OEE) of the packaging lines has come under the microscope. This includes packaging of all the products in the Nicorette family, as well as for other products manufactured on-site, which include Microlax, an enema, and for Treo, the long established Swedish effervescent pain relief tablets. Annette Cederhag, Project Manager in the Engineering Maintenance Utility at McNeil, Helsingborg, explained: *“For many years we had used a hand-written logging system of faults on the 32 automated packaging lines for all the healthcare products we manufacture here. As we operate 3 shifts 24/7, it is very important that we minimise downtime. The packaging machines were not designed to provide a sufficient variety of error code data to give us the detailed information we needed.”*

Solutions

- Production Management
- OEE
- Management reporting

Products

- Proficy Plant Applications
- Proficy Historian
- iFIX HMI/SCADA

Results

- Accurate downtime logging
- Data 'released' to improve OEE
- Downtime data available in real time
- Management reporting via intranet
- Open Proficy software enables future system enhancements

Benefits

- It helps to identify and improve areas that are causing operational inefficiencies
- It allows analyses of root causes to make data-driven decisions
- It manages operations in real-time through comprehensive reporting, which can be made accessible via the web
- Gradual implementation of new lines

"Inevitably it was very difficult to try to obtain any true analysis of downtime, so we approached several automation suppliers in Sweden for a system that would give us the capabilities we were looking for.

"The pilot projects ran in parallel for 8 months. Right from the start we consulted with our packaging operators. We have worked with them all the way from initial investigations, through the pilot projects, and through the eventual conversion to our new system. The operators' input was invaluable and, of course, they have to operate the new technology so it was important that we developed a system they understood and that they felt they could work with."

Downtime information "released" by Proficy Plant Applications

The Downtime Information Reporting System (DIRS) that was eventually developed is based on the Efficiency module of GE Digital's Proficy Plant Applications plant performance analysis and execution software. Explaining the decision Annette Cederhag, commented: *"The local Systems Integrator, Novotek Sverige AB, proved to be an excellent partner throughout the pilot project and during the conversion to the live system. They had many good ideas which we were able to implement throughout the pilot scheme as it developed. Proficy Plant Applications provides the data analysis capability we were looking for, together with the ability to interrogate the system in real time via the McNeil intranet from any authorised location."*

The DIRS provides a tool that helps the organisation to identify the source of breakdowns, problems during shift changeovers, and other disturbances that impact the OEE, and hence productivity, of the healthcare product packaging lines. Cederhag continued: *"The packaging systems are very diverse. Over 1000 different items are used for packaging.*

They include encapsulation of Nicorette gum, Nicorette Freshmint Gum and Treo tablets, followed by boxing and wrapping. Other processes include boxing of inhalers and spray dispensers. Boxes are date stamped, etc., and encapsulated in larger batches and put in boxes for bulk delivery to locations throughout the world." At the time of writing, 15 lines had been converted to the new DIRS. With pilots originally running on 5 lines, modifications had gradually been implemented and good practice acquired so that transfer to the live system was straightforward. New lines have been going live at 5-week intervals, with plans to accelerate the changeovers to 2-week intervals for the remaining 17 lines.

The Downtime Information Reporting System was added to the existing LAN which links into the company's intranet. The operators' terminals, usually one per packaging line except where the line is particularly long when there may be two, act as thin clients to a terminal server. A second terminal server provides redundancy for immediate back up should there be a problem with the first server. Mats Blohm, Automation Engineer in Engineering, Maintenance & Utilities, explained: *"This system runs under iFIX HMI/SCADA. The thin clients act as HMI inputs with a selection of on-screen buttons appropriate to the packaging line. These touchscreen buttons provide rapid input options for logging faults on the packaging line. This data, together with time stamping provided via the packaging machine's PLC, is captured and logged on the Proficy Historian database used by the whole production facility."*



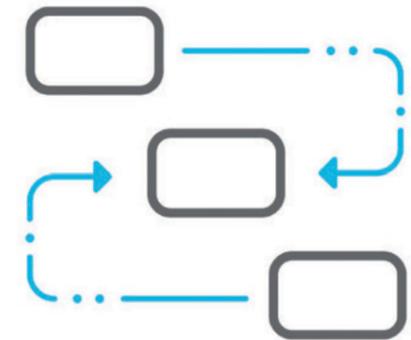
Real-time data on the intranet

"The Efficiency module of Proficy Plant Applications is now able to access this data and share it in real-time or as historical data with users at all levels on the intranet," he continued. "Each operator screen, for example, displays a table of the recent interruptions on that packaging line. Management reports can be accessed on the intranet by any authorised person. A wide range of analyses and charts is possible. For example, by packaging line, by fault type, by downtime length. From this, it is now possible to get an accurate picture of what are causing inefficiencies on each line so that the appropriate actions can be taken to increase Overall Equipment Efficiency."

As a pharmaceutical and health-care product manufacturer, McNeil follows the Good Manufacturing Practice (GMP) code of working. This ensures the overall quality of its products and is based on the positive effect, the purity, identity, strength, the production flow and procedures adopted. Standard Operating Procedures ensure that every batch of products at Helsingborg is sampled randomly, at the beginning in the middle and at the end. Stringent quality control tests have to be passed for purity, packaging, labelling, etc., before that batch is allowed to leave the plant. GMP also ensures that the company works well within the local and national environmental and health and safety requirements.

Proficy Plant Applications

The Efficiency module enables users to better utilize plant assets by providing a comprehensive view of Overall Equipment Efficiency (OEE). It is the ideal solution for managers trying to increase throughput without adding equipment, people or material costs.

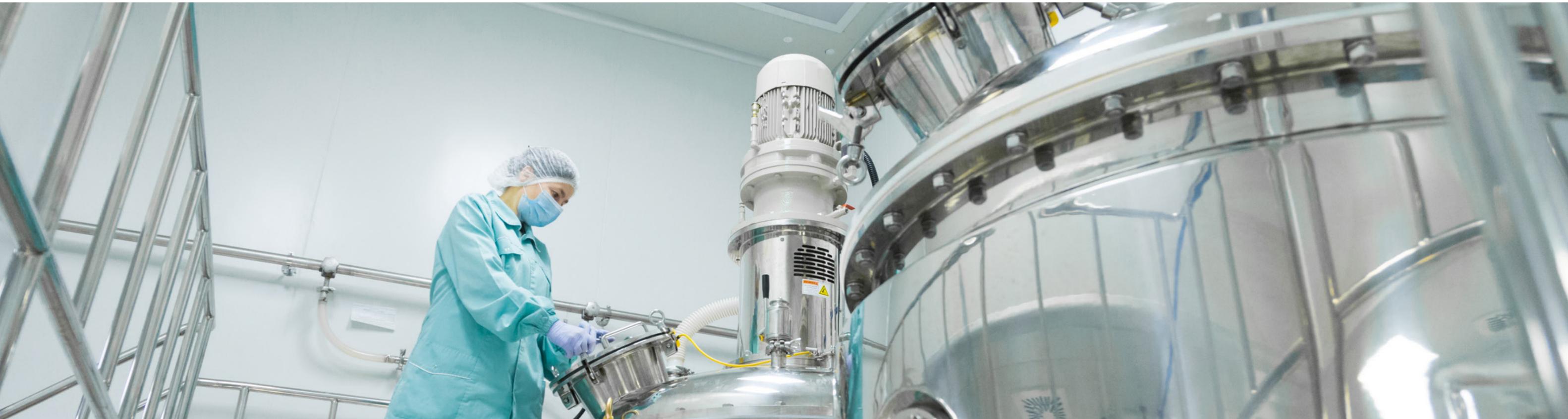


"By choosing GE's software we have the reassurance of long term product support. We have been able to develop a customised solution, paying only for the elements we need. But it offers much more. Looking to the longer term, the package we are using is just one element in the complete Proficy intelligent production management suite of open programs. We can now look at our manufacturing lines with a view to easy integration using other parts of the suite."

— **Annette Cederhag,**
Project manager Engineering Maintenance Utility, McNeil

North American Pharmaceutical Company

Implements Electronic Quality Checks and Corrective Actions



North American Pharmaceutical Company

Electronic Quality Check

Corrective Actions On Out-of-Spec Product

A lack of efficiency with manual/paper processes meant that the company experienced slow resolution of quality issues. Operators were doing quality checks manually with a paper grid. Proficy Workflow improved efficiency by automating the quality checks and initiating corrective action— as an addition to the company's existing GE Digital HMI/SCADA systems. Proficy Historian provides data collection, archiving, and distribution for analysis. The company also uses Proficy Plant Applications as its standard Manufacturing Execution System (MES) along with Proficy Batch Execution. Proficy CSense includes a closed-loop with analysis for process optimization.



Solutions

- Proficy Workflow
- iFIX HMI/SCADA
- Proficy Batch Execution
- CIMPLICITY HMI/SCADA
- Proficy Plant Applications
- Proficy Historian
- Proficy CSense
- Proficy WebSpace

Results

- Improved efficiency
- Reduced waste and costs
- Better quality information
- Faster resolution of quality issues





Pfizer Newbridge drives business value with integrated automation



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

Solutions

- iFIX HMI/SCADA
 - Proficy Batch Execution
 - Proficy Plant Applications
 - Proficy Historian
-

Challenges

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 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 Digital across both of its facilities for MHTs (Menopausal Health Therapy) and OCs (Oral Contraceptives).



Results

- 25% reduction in expansion lead-time
- 23% reduction in resources
- 20% reduction in investigation time
- Reduced time to maintain
- “Plug and Play” flexibility
- Increased scalability
- Automated “OEE for Batch”



Solutions

A Technical Approach to HMI/SCADA, Batch Execution, and MES

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

The controller and SCADA standards are closely coupled to truly realize the power of the Batch Engine used to control production. The team selected iFIX HMI/SCADA and Proficy Batch Execution from GE Digital 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 paperwork. Our class-based approach has also led to greater repeatability.”

— Eoin McMahon, Automation Engineer,
MHT Pfizer Newbridge



The Technical Journey

iFIX HMI/SCADA and Proficy Batch Execution in Pharmaceutical

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 Execution 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 Electronic Batch Records (EBR)
- Real-time monitoring of exceptions occurring during the manufacturing process

“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 vendors’ facilities. 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 crossover.”

— Alan Shefflin,
Automation Site Lead



Support

On-Site Services for HMI/SCADA and Batch Pharmaceutical Implementation

The site also understood the benefit of having GE on the ground. From early on in the project phase, Pfizer involved GE's services 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-by-Design Data

Plant-Wide Historian for Pharmaceutical Manufacturing

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 Digital's Proficy Historian. The site DHS incorporates 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.”

— **Michael Howell,**
Operations Lead, MHT Operations, Pfizer Newbridge Ireland

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-by-design 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 iFIX thin clients across the floor deployed with Citrix Technology.

Building Management

Building Management Systems in Pharmaceutical Manufacturing

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.

Manufacturing Execution

MES and EBR in Pharmaceutical Manufacturing

To gain the most value from the highly integrated automation system, a Manufacturing Execution System (MES) solution was incorporated into the plant design to:

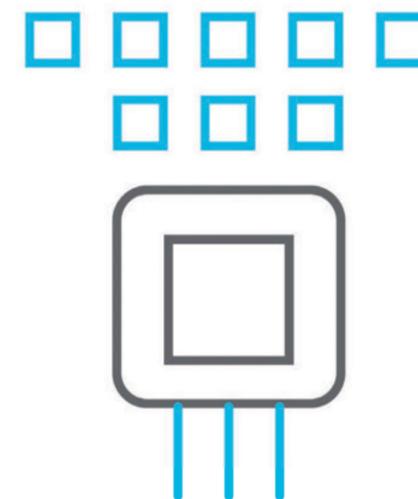
- Provide functionality through Electronic Batch Records (EBR) to guide the production in conformance to the batch record
- Ensure acknowledgement and commenting of Level 1, Good Manufacturing Practice (GMP) alarms during batch processing

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 Proficy Batch Execution system-enabling the process equipment to automatically request a load or unload during a recipe cycle.

With a standardized controller 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 led 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.”

— Eoin McMahon, Automation Engineer,
MHT Pfizer Newbridge



Learning

Batch Execution Adds Manufacturing Capacity

One of the biggest lessons learned was in the area of controller and phase logic. Proficy 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 controller and SCADA through to Batch.

“The standards we have invested in, and evolved, can now be used to scale up our existing facility. 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.”

— **Fergal McTiernan**
Engineering Manager, Pfizer Newbridge

The Future

OEE for Batch Execution and Batch Analysis in Pharmaceutical Manufacturing

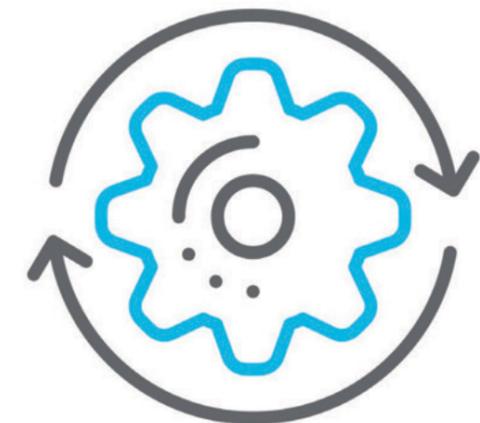
“We are now looking to take the next steps with our N-SmarT (Newbridge System of Manageable Automated Results for TPM) program and are piloting an Overall Equipment Effectiveness (OEE) for Batch on our coater using Proficy Plant Applications in partnership with GE,” said Paul Conroy, MHT OE Lead. *“The 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 Proficy Plant Applications 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 this concept.

“We also aim to leverage our investment made with GE and Proficy Plant Applications to aid in the site-wide water reduction program,” Howell concluded.

“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





**CONTROL
ENGINEERING**

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Pfizer – Vega Baja, Puerto Rico

Building Manufacturing Efficiency



ARTICLE BY:

**Jose Marrero Diaz, Latin American & Puerto Rico region
IT Director/Team Leader, Pfizer**

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Today, many pharmaceutical plants typically operate at somewhere around 30% efficiency, with a few world-class operations reaching the 70% range. However, even these stars fall below the levels that other well-run conventional process manufacturing operations achieve, where efficiencies of over 90% are routine.

Globalization is forcing all companies, and especially pharmaceutical industries, to develop competitiveness strategies and deploy them quickly if they expect to remain in business.

All this tells us that we must not only look aggressively for ways to make our manufacturing operations competitive, but also deploy the technologies that will allow us to measure and substantiate that competitive advantage. Pfizer has found a way to put such processes into practice, with exceptional benefits.

Overall equipment effectiveness (OEE) is a key metric that many companies are using to measure plant or line efficiency. OEE calculation results can be used for many operational diagnostics:

- Understand how well we are performing with an objective yardstick;
- Identify and eliminate constraints;
- Define target areas for improvement; and
- Align those targets with larger business strategy.

OEE measurements allow managers to make more effective, more objective, and more informed decisions in real time.

In November, the Pfizer facility in Vega Baja, Puerto Rico formed a cross-functional team to focus on creating more competitive costs through implementing an OEE data gathering and reporting system.

This important initiative, a collaborative effort between the regional manufacturing engineering and technology (ME&T) team, IT, and Vega Baja packaging teams, set out to improve data collection and visibility for determining OEE for packaging lines in the Puerto Rico region. This initiative was identified as critical and imperative to manufacturing success in today's dynamic business environment.

Crude but effective

Experiences with OEE in the Vega Baja facilities started out as manual processes developed by Juan C. Figueroa, a packaging technical specialist, and Xavier Schlienger, a packaging team leader, when they implemented it successfully at two blister lines.

While the manual system was cumbersome, the value of the information it generated was clear, so the next step was to move the process to the next level and see how data collection could be automated. That process began with automating the forms but still having operators enter data manually into the terminals. This reduced the amount of data entry, provided OEE metrics much sooner, and generally improved the quality of the process.

In December, Figueroa joined Jose Santos, Mark Poham, Vik Sharma and Edwin Rivera in an effort to develop and implement a still more user-friendly system to collect additional OEE data that would provide visibility of the results

to the shop floor operators and also to management. One of the major long-term requirements of the project was building in capabilities for the system to gather real time data directly from the equipment and be expandable to other areas of the manufacturing process.

Pfizer global manufacturing (PGM) corporate IT had worked on the development of a manufacturing data reporting system called PfindIT (Pfizer factory intelligence network dashboard-IT), but the system lacked a user-friendly graphical interface and OEE reports. A team consisting of colleagues from PGM IT, regional IT, and packaging was assembled to define user requirements and work with the system vendor to develop the graphical user interface and reports required.

The team brought in long-time vendor partner GE to assist with the project. GE's production management software system, Proficy Plant Applications, has an efficiency module that seemed to fit the bill. This module is able to identify and monitor all areas of manufacturing for inefficiencies, perform root cause analyses, compile historical data summaries, schedule reports, and control OEE.

The biggest challenge was to complete the development and deployment by the first quarter. Working over the year-end holidays, the team completed a pilot system in one of the packaging lines in Vega Baja which was working in January. Deployments then continued with the rest of the 12 packaging lines. The tool was accepted by the shop floor operators immediately, setting off a wave of friendly competition between operators to demonstrate whose line was the most efficient.



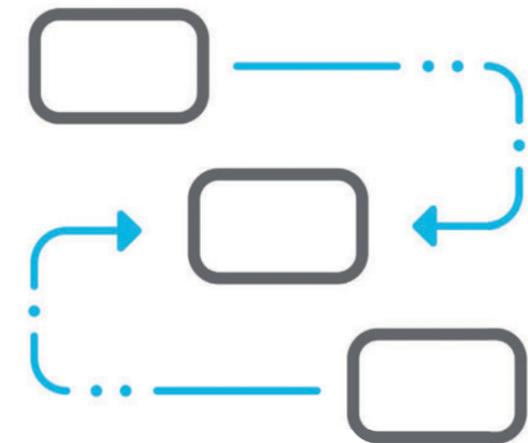
Implementing the new system brought a higher level of measurement consistency across the business. Different departments and sites had created their own techniques which made for results that could not be compared directly. With the new system in place, data collection was restructured for uniformity and aligned with the goals of the business. For the sake of consistency, the global packaging team with the help of Pfizer global engineering (PGE) defined two standard OEE calculations that are currently integrated into the system.

Real results, OEE

Watching improvements from these efforts is very rewarding. OEE numbers were only around 30%. But after, we were hitting 50% consistently, which is more than a 50% overall improvement. Perhaps that doesn't look like much, but an OEE of 30% is equal to 2.4 hours of productive time, while an OEE of 50% equals 4.0 hours of productive time, an improvement of 1.6 hours. The OEE monitoring system provides a tool for operators and supervisors to target areas of improvement continuously. We expect even higher savings since standard hours required to operate two packaging lines were reduced by 40% per line per shift. This is an example of the type of continuous improvement possible and achievable once you have visibility of your process and operations.

The development of the system has been such a success that the global packaging team has adopted it as the official tool for OEE measurement. Other Pfizer sites in Latin America, including Puerto Rico, Mexico, and Brazil have evaluated how they can implement the system as a way to build the competitive advantages within the Pfizer network.

The team next worked on Phase II of the project to collect data automatically, directly from shop floor PLCs and SCADA systems. The collaboration in this project has proven to be an excellent demonstration of what "One IT" is all about.



Reckitt Benckiser Optimizes Its Control System with Batch Execution Systems



Reckitt Benckiser

Reckitt Benckiser is a manufacturer for over-the-counter health and wellbeing products. Its manufacturing facility mixes, blends, and packs an over-the-counter branded indigestion remedy into glass bottles, stick packs, and tablets in 6,000 liter batches.

Challenges

Analysis, prognosis, and prescription

Astec Solutions, a GE Digital partner, was called in to help Reckitt Benckiser improve the performance of their manufacturing control system. The facility mixes, blends, and packs an over-the-counter branded indigestion remedy into glass bottles, stick packs, and tablets in 6,000 liter batches. Unexpected system crashes cost 30-90 minutes for every batch and system restarts had to be performed in a strictly regimented way, or entire batches of product could be lost. The system, which was installed by a system integrator six years previously, used GE Digital products in its architecture.

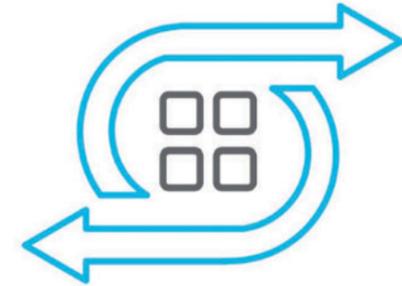
“After raw materials were mixed and blended they were transferred to storage tanks, before being sent to the packing lines,” said Chris Barlow, Technical Director, Astec Solutions. Up to seven filling lines can be connected to the storage tanks. *“The system had not had a major update since installation. It was slow, unstable, suffered from periods of unscheduled downtime and was not producing reliable data. It was becoming a risk to the profitability of the site.”*

The regular breakdowns were dealt with by giving the initial integrator the authority to call in and restart the system — a ‘sticking plaster’ solution that had been in place for three years.

The first step was to speak to the operators and gain a clear understanding of how the problems manifested. The Astec team also ensured the clear identification of the client’s objectives and ideals. Unsurprisingly, avoiding breakdowns and minimizing downtime topped the list, as they most obviously affected operations, production and revenues.

“We looked at the system’s architecture and analyzed the log files in order to identify errors in the system,” he said. Astec had to work around the needs of a facility that was still in full production, so that process took around 10 days. Its first proposal was a slight change to the system’s physical architecture. The servers were located in a control room and were subject to knocks and kicks, as well as being exposed to dust originating from the production process itself. The recommendation was to relocate them to an on-site data center, safe from accidental damage and atmospheric pollution. The next task was the software architecture.

“The previous integrator had implemented some of their own bespoke software components, in order to integrate the solution,” said Barlow. *“In effect, the architecture had been ‘bent to fit’ and it was not ultimately the best solution.”*



“Production had grown beyond the original solution, so demands were also a lot higher. The time was right to review and upgrade the whole solution. But it had to be achieved without shutting the factory down.”

— **Chris Barlow - Technical Director,**
Astec Solutions

Solutions

Astec's team recommended that Reckitt Benckiser should:

- Implement the latest versions of GE Digital's Proficy Batch Execution software as well as iFIX HMI/SCADA and Proficy Historian
- Remove the bespoke applications and configure the GE Digital solution to undertake those tasks itself
- Separate out the relational database and make them standalone, distinct from the Batch Execution software
- Implement Microsoft SQL Server Reporting Services (SSRS) in order to provide the customer with a reporting platform that was scalable, and could be enhanced and updated with additional reports as required

Implementation had to be achieved without interrupting production. Most of the work was undertaken between the hours of 2:00 am and 6:00 am, when the first daily shift arrived to start work. The process of preparation involved configuring all the hardware, then installing the software and checking connectivity.

We undertook bench testing and a lot of software preparation. When it came to the point of implementation we were pretty confident that it would work first time – and it did. It worked properly right from outset.

— **Chris Barlow - Technical Director,
Astec Solutions**

Results

GE Digital's integration, upgrade, and improvement enabled the customer to boost output and reliability. Specifically, it was able to end random offline incidents and unexplained crashes, as well as improved data collection. With the new system, the manufacturer was able to deliver accurate performance reporting, production analysis, and batch reporting.

The upgrade also extended the reporting platform with Microsoft SQL to other areas of the plant, providing a site-wide database for reporting. These new capabilities enabled the manufacturer to:

- Reduce risk, improve production stability and boost product quality, consistency, and traceability
- Immediately cut maintenance expenditure
- Minimize the cost of rebooting the system after crashes, which is estimated to cost more than £50,000 per year





About GE

GE (NYSE: GE) is the world's Digital Industrial Company, transforming industry with software-defined machines and solutions that are connected, responsive and predictive. GE is organized around a global exchange of knowledge, the "GE Store," through which each business shares and accesses the same technology, markets, structure and intellect. Each invention further fuels innovation and application across our industrial sectors. With people, services, technology and scale, GE delivers better outcomes for customers by speaking the language of industry.

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