



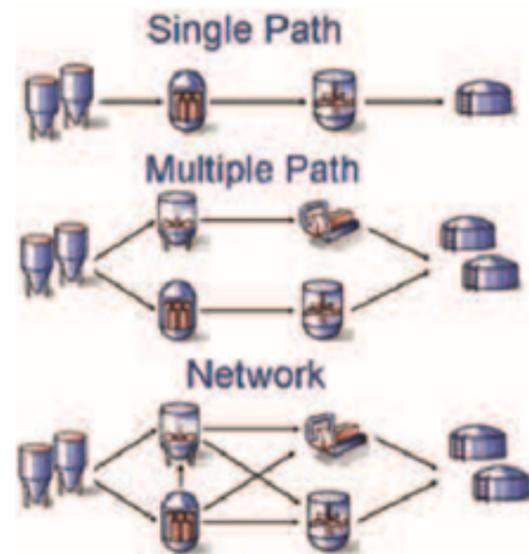
Implementation of a Batch Tool in the Pharmaceutical Industry

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continuous and discrete processes, within the process cell (Process Cell) the product can pass through several devices arranged in sequence, which can have a fixed (single path), variable (multi path) or network arrangement (network), as shown in the figure below.



Regardless of the type of equipment arrangement at the plant, they all allow batches to be produced in parallel, whether of the same or different products. To make the most of parallel runs, it is possible to connect the corporate system with the system that manages the dynamic allocation of equipment in the process. Thus, it is possible to scale the production capacity closer to reality and make production planning more efficient.

Pharmaceutical Industry

In general, the pharmaceutical industry has a research and development sector focused on innovation and the creation of new drugs that prevent the spread of epidemics and / or help to improve the quality of life of the population.

The way to reach the formula for a drug that does not exist on the market or that is more effective, is not always simple, nor fast. Most of the research takes years, and there is not always a guarantee that at the end the result will be a drug that can be commercialized. For laboratories, this entire research cycle is treated as an investment sponsored by a percentage of the revenue from products already consolidated on the market. The increase in the production of existing drugs and the optimization of the resources used in their manufacture can generate a profit that can be directed to specific research and, consequently, accelerate the process of obtaining the results.

To monitor the laboratories and establish manufacturing standards that ensure the health of consumers, there are regulatory bodies in each country or continent, responsible for organizing audits in production environments. In Brazil, ANVISA (National Health Surveillance Agency) is responsible for evaluating and monitoring the manufacturing processes of the laboratories. However, if a Brazilian laboratory wants to export its medicine, it must comply with regulations established by agencies in other countries.

In order to facilitate the testing of the necessary functionalities of a manufacturing system, as well as its adherence to industry regulations, a group of pharmacists from ISPE (International Society for Pharmaceutical Engineering) created a methodology with good practices called GAMP (Good Automated Manufacturing Practice) [Ref. 2]. The GAMP provides guides on how to comply with good cleaning practices, good electronic data storage practices, good control systems validation practices, among other guides.

There is a term widely used in the pharmaceutical segment referred to as validation. Validation is nothing more than

proving, through tests, that the implemented configurations satisfy the required needs. Despite the simple definition, validation is a process that is treated with great caution and can take a long time, depending on the size and complexity of the system. All necessary care must be taken with a system that has already been validated, since any change in the configuration that may affect or alter its operation may result in the need to revalidate it.

To ensure the traceability and safety of changes made in the process, there is a rule published by the FDA (Food and Drug Administration) called 21 CFR Part 11 [Ref. 3]. This standard refers to electronic signatures and establishes that all electronic records must be inviolable, and their integrity must be maintained in such a way that it is possible to identify who performed an operation, at what time and what was the alteration practiced.

Gathering all this important information and standards that must be applied in the Brazilian market, ANVISA together with members of ISPE Brasil, created the document called the Computerized Systems Validation Guide [Ref. 4].

Implementation of a Batch System in the Laboratory Aché

Aché Laboratórios Farmacêuticos S.A. is a 100% national capital company. Along its trajectory of more than four decades, Aché has consolidated itself as a dynamic company by establishing strategic commercial partnerships, inside and outside the country, for its expertise in similar medicines, management of a mature portfolio, knowledge of the Brazilian consumer market, and for the continuous development of products and services, in order to meet the needs of health professionals and consumers, providing health and well-being to the population.

Data Visualization

It is important to note that the data can be accessed in reports and graphical screens of Proficy, through a computer using company-approved Internet browsers, or from Proficy Historian, which is the database, of two ways: via an OLE DB query - the user must be registered in the database with read access - or using the Microsoft Excel tool (Figure 6), through a plug-in.

It is an add-in offered by Proficy Historian, which is installed in Excel and allows you to connect to the database. It makes it possible, directly in Excel: to search for server tags; update values in real time; create reports; create historical or trend graphics; perform statistical analysis of the data, etc., in addition to allowing access to the data according to the user's profile.

In fact, not all users who have access to the Proficy dashboard/portal have access to Proficy Historian via Microsoft Excel, whose access is more restrictive and much more used by maintenance and process users in technical and engineering operations. The idea of accessing Proficy Historian through Microsoft Excel is the possibility for the user to do a dynamic search and create their own reports instantly.

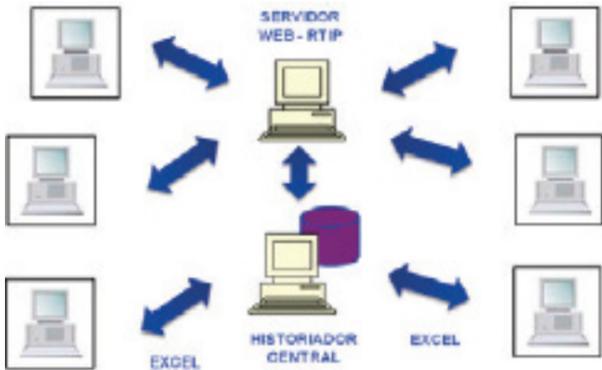


Figure 6 - Access to Proficy Historian through Microsoft Excel

Cabiúnas Terminal

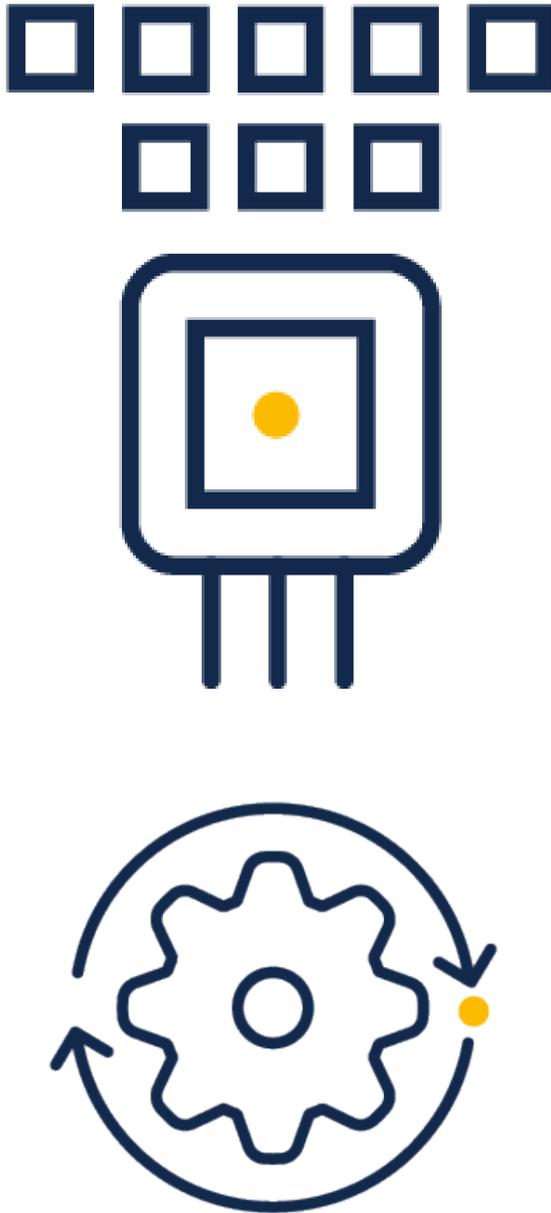
During the InfoSCADA implementation process, an extra need arose. For the Cabiúnas Terminal - which is the largest natural gas processing hub located in Macaé / RJ - it was necessary to expand servers and, therefore, adopt a local historian, exclusively for local data storage.

The Cabiúnas Terminal stores and transfers approximately 15% of the oil, processing part of the natural gas produced in the Campos Basin. Its processing capacity is 19.7 million m³ / day of gas and 4.5 thousand m³ / day of gas condensate. It consists of three URLs (Uindade de Recuperação de Líquidos - Liquid Recovery Unit), three UPCGNs (Unidade de Processamento de Condensado de Gás Natural - Natural Gas Condensate Processing Unit) and one URGN (Unidade de Resfriamento de Gás Natural - Natural Gas Cooling Unit).

Due to the large number of points, it was necessary to have a larger dedicated database to communicate. The architecture of iFIX at the Cabiúnas Terminal is made up of six pairs of SCADA servers, with 70 clients and three server terminals, with a license of 10 each for remote access, totaling today around 48,000 tags, adding all these six pairs.

The iFIX servers send their data to Proficy Historian, which acts as a local server, providing data to the Cabiúnas operating stations, and a server-to-server connection is made from the Historian of Cabiúnas to the Historian of PIMS of InfoSCADA.

The benefits of this solution in Cabiúnas have proved to be quite positive, especially since the amount of intelligent instrumentation data is now much greater than simply the process data itself. The equipment data is even more voluminous than the process data itself.



Successful Application: Maintenance

One of the areas that has benefited greatly from the implementation of InfoSCADA is maintenance. Before the new system, the data could only be accessed by the CNCO operating system, that is, to obtain the data and perform some monitoring of the variables – such as pressure, flow and temperature of the notable points, it was necessary to ask the operators of the CNCO database or a trend to carry out the study and still call the CNCO to obtain the status of some variable. This did not even allow, in some cases, preventive action to maintain the operational bases.

As previously mentioned, the Mesh Management indicated technicians to be trained as developers, and the screens were developed in conjunction with the CNCO team. As the screens were being developed, users were informed and started using them as a reference.

The fact that the entire system already made available the data of the field variables in the CNCO database was an easiness for the developer, who only requested registration, “history the variables,” the data and then the variables were available to implement the screens.

InfoSCADA is today one of the best tools for monitoring maintenance, as well as for optimizing maintenance planning. Transpetro's operational bases precede the problems using the information provided by the system.

Daily, the operational bases scan all monitored points, checking the variables and programming technicians to act when abnormalities are identified. As a result, the risk of failure to deliver to customers was reduced, as well as the number of out-of-office visits, which often had an impact on the next day's schedule.

The gas pipelines are 100% operated by the National Center for Operational Control. There is no supervisory in the field. Thus, when maintenance technicians went to the delivery point (a station where the pressure of the duct is reduced and the gas is delivered to the local distributor), they were unaware of the data of the devices at that delivery point. To facilitate the work, the maintenance field team developed a screen (figure 7) identical to the one used at CNCO, including the data acquired from InfoSCADA. With this, in order to know the status of the signals at the delivery point, the maintenance technician, using a laptop with wireless communication and a token to access the Petrobras corporate network, access the InfoSCADA portal and visualize all data on field.

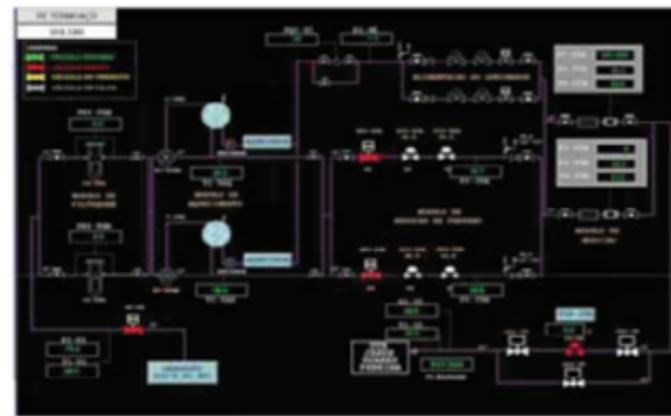


Figure 7 - One of the screens developed by the maintenance team

Conclusions

To summarize, one of the main gains for Transpetro was being able to convert the data online into historical data, which can be used in the future. The potential for using historical data is enormous, especially regarding analysis of specific operations or products. InfoSCADA is a concrete example of the integration of the worlds of Information Technology and Automation Technology.

The benefits achieved by Transpetro with the development and implementation of InfoSCADA, using Proficy Historian and the Proficy dashboard/portal software, include:

- General view of all oil and gas pipelines and terminals on a single data server, allowing to see all Transpetro logistics in a single system
- Consolidation of information to optimize logistics (especially quantities in oil and gas pipelines)
- Access to field data in real time from Petrobras' corporate network
- Graphical analysis of data for long periods of time
- Calculation of process efficiency indexes for monitoring
- Security: data access profiles, password synchronization with the domain and access to screens and tags according to the user's access profile
- Low system acquisition and maintenance cost compared to other software
- Compatibility with iFIX HMI/SCADA systems used in Terminals and Compression Stations, with no need to purchase hardware in the field
- Ease of training screen developers (in eight-hour training only)

In the future, Transpetro intends to integrate, in addition to terminals, oil and gas pipelines, also data from oil tankers to InfoSCADA, where other types of collectors will be needed and are already being tested.

The company also foresees the expansion of Historian server hardware and the integration of other systems that make use of the data stored in InfoSCADA.



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About GE

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