



## Movicon in the largest pharmaceutical production plant in Brazil

Prati-Donaduzzi is the largest pharmaceutical company in Brazil in manufacturing generic drugs. It has recently been revamped with a new supervision system to control and monitor its manufacturing plant.

Prati-Donaduzzi is a major Brazilian pharmaceutical company and is the biggest manufacturer of generic medicine. Alone it provides a third of the nation's generic drug production supply.

Prati-Donaduzzi's history is built on pillars of devotion to the quality of its pharmaceutical products and commitment to valuing human resources, ethics and integrity.

### Company History

After returning home with Master Degrees obtained by studying in France in the late 80's, the Pharmacist couple Luiz and Carmen Donaduzzi set up an activity to produce medicine by building a pharmaceutical manufacturing plant in the capital of Pernambuco, Recife (Brazil).

In 1993, with the support of the Toledo Council (a city in the Paraná state of Brazil) and the Paraná state government, the company went into operation in the city of Toledo with the objective to increase its activities based on acquired quality and expertise. The company originally started its activity to manufacture drugs for hospitals but its key vision was to search for new opportunities in the domestic pharmaceutical market in Brazil that, according to law, accepted the production and use of generic drugs (Law no. 9.787, February 10<sup>th</sup>, 1999). Prati-Donaduzzi soon started making its way to the top of the Brazilian generic drug market by promoting its expertise, quality and innovation. This was done by constantly developing its production to become the most important generic drug manufacturer in Brazil today. The company is now the largest drug supplier to government health agencies in Brazil with an annual production of over 11 billion pharmaceutical doses.

### Generic Drugs

Generic drugs are the equivalent to brand-name drugs whose patent for exclusivity has expired. They are an exact copy of their brand name drug counterpart in dosage form, safety and strength, route of administration, performance characteristics and intended use. Therefore, they are a more affordable option and can be interchanged with their brand-name counterpart. A majority of countries support and encourage the use of generic drugs by making them more accessible and affordable for public use. The interchangeability or rather the safe substitution of a brand name drug with an equivalent generic drug is only possible if first bioequivalently tested and approved by the Ministry of Health's national health surveillance agency. Only after approval has been given can the generic drug be made available to the public through pharmacist recommendation or doctor's prescription.



*The Prati Donaduzzi establishment in Toledo (Brazil), produces 33% of Brazil's demand for generic drugs.*

### The production site's Supervision System

The company has recently integrated various production plant systems and subsystems in one unique integrated supervision system that is capable of monitoring and controlling the following systems:

**HVAC**- Heating, Ventilation and Air Conditioning

**EMS** - Environmental Monitoring System

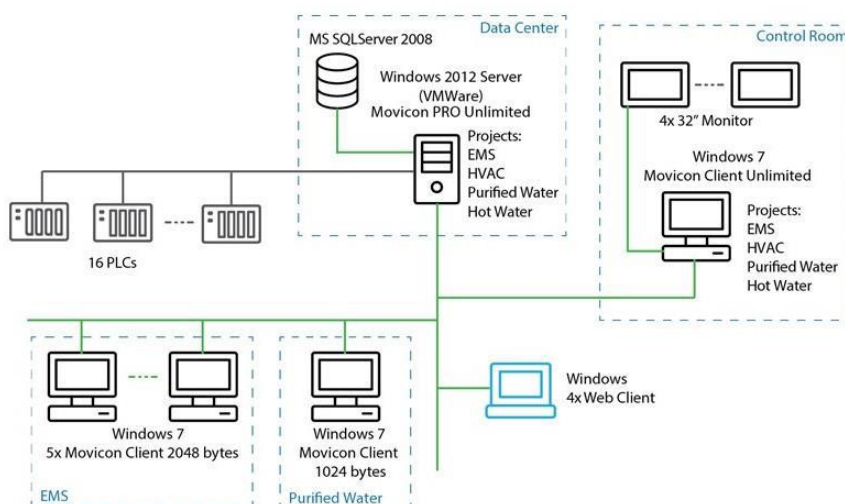
**PW** - Purified Water

**CA** - Compressed Air

**HW** - Hot Water

The various control systems are distributed throughout the production plant's local network that includes 16 Eurotherm T2550 PLCs connected with the OPC technology by implementing over 6,500 variables.

Another six Movicon Client workstations are connected to the main control system and used together with sub-control systems to enable field operativity. The users (operators, maintenance workers, production managers and personnel) can connect by remote control using the Movicon Web Client technology with any browser or mobile device such as Tablet or Smartphone. There are more than 200 users currently registered with the Centralized Users and Passwords management. These users are various personnel who have been assigned authentication based on the various hierarchy levels. This allows them access to interact with the control system according to their authorized level of competence in the company. The diagram below illustrates the supervision system structure:



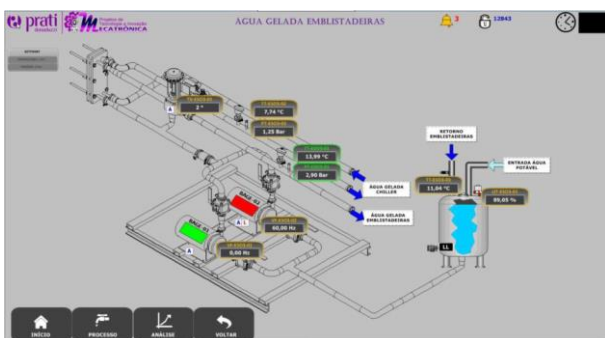
A server, based on the Windows 2012 Server, resides in the plant's Data Center room as a virtual machine (VM) with Ms SQL Server 2008. The Movicon 11 SCADA server is ran unmanned on the server workstation in the Data Center room. Operator control panels are located in the Control room together with the Movicon Client workstation and four big monitors to give operators full control of the plant.

### Plant management

The management of the whole plant infrastructure is essential to ensure that the productivity processes are efficient with the quality needed to comply with the strict safety norms governing the pharmaceutical production sector. Besides each individual production line or machine, each with its own automation system, the infrastructure's facilities, if not managed correctly can affect the process of the whole production chain. It is for this reason that Prati-Donaduzzi has invested in installing systems and procedures that ensure the maintenance of productivity, quality and safety.

The Ventilation and Air Conditioning system (**HVAC**) of the entire plant encompasses all the heating, ventilation and air conditioning systems. Those systems belonging to this category are those that use a large amount of electricity. By managing the use of these systems properly, it is possible to save up to 50% on electricity bills over the duration of one year. This is a very significant save considering that the temperature of many areas in the drug manufacturing plant have to be vigorously controlled. It is crucial that the air conditioning parameters are kept stable within their limits to avoid sudden changes in temperature that may adversely affect production. The **Water Purification** management (PW) is also extremely important in every sector of the pharmaceutical industry. This is because it is applied as the basis of all liquid medicine such as syrups and injectable drugs.

The **Hot Water** (HW) systems are also just as important in the pharmaceutical production process and are tightly connected. Optimal temperature maintenance for each individual production process is a major factor that determines the maximum quality and precision of the final product. The **Compressed Air systems** (CA) are comprised of sophisticated compressors that generate sterilized air that is completely dry and void of dust particles, oil and moisture as required by the strict standards governing the pharmaceutical industry. Consider that 1 m<sup>3</sup> of untreated air contains up to 180 million dust particles and 50% to 80% of moisture and oil in the form of unburned hydrocarbons. The compression process increases the concentration of these particles and when compression reaches, for example, the 10th bar, the concentration of these pollutants multiplies by 11.



*Some of the many Movicon supervisory graphical screen pages through which operators can monitor and control the various systems and EMS*

The purified water loops are used in the production process to distribute the water to different drug production points in the factory. Each distribution PW loop consists of a storage tank where two pumps work in parallel and alternate to ensure that pressure is kept at a safe level throughout the loop. The pumps are equipped with a frequency inverter that is controlled by a pressure probe and flow meter to permit pressure continuity independently from the number of user points opened. Ultimately, the Movicon supervisory system must also manage the entire **Environmental**

This means that in every 1 m<sup>3</sup> of compressed air there are about 2 billion dust particles. Therefore Compressed Air systems are critical to large pharmaceutical industries and just as crucial as the other systems to ensure safe and correct drug production management.

**Monitoring System - EMS.** This system is an application used to monitor the whole environment with alarm level management and documentation and safe recording and measuring of collected data from each process. The recording of data on database constitutes as valid electronic documentation for legal purposes in order to certify the proper conduct of the whole production process according to the current rules and regulations endorsed by the law.

This system offers the operator non-stop control in real-time of the whole plant by displaying all potentially dangerous events clearly and immediately on graphical screen pages.

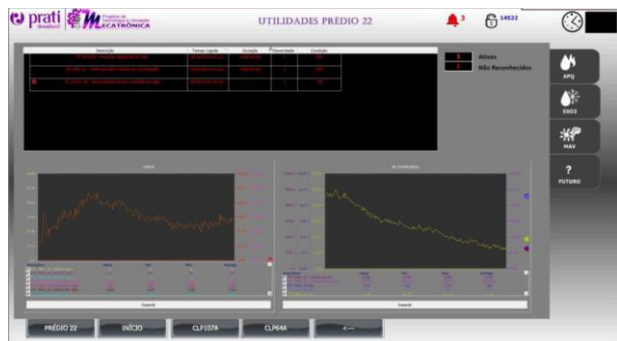
**FDA CFR21 Part 11 validation** This project has been design engineered to conform with the strict Food and Drugs Administration rules and regulations according to the CFR21 Part 11 norm.

The design engineers' work was facilitated by using the features offered by Movicon a SCADA platform specifically designed to fully support both the American FDA and European GAMP norms.

The pharmaceutical plant system validation was one of the project's key demands, not only for the criticality of the components that needed managing, but also to ensure the renowned product quality that has always distinguished the Prati-Donaduzzi company in this sector.

**Achieved Results**

Prati-Donaduzzi is highly satisfied with the end results by declaring the project to be a complete success. In order to cause as little impact as possible to productivity, the project only took two months to design, test run and validate according to the FDA norms. Thanks to the Movicon technology, the client reached their goals well within the official deadline. Prati-Donaduzzi realized this project by assigning it to a team of four engineers who were supported by Exata Sistemas de Automação, a Progea partner since 2008.



*The supervision system records all the process data and parameters with CFR21-Part 11 validation*

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*“We are very satisfied with the project” confirms **Edison Brustolin** and **Michel Adur**, the Prati-Donaduzzi project managers. “The Movicon 11 SCADA technology has proven to be stable with optimal performance and very easy to maintain”*

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*A big thank you to  
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