

MONITORING PROVIDES PROCESS VALIDATION IN THE PHARMACEUTICAL INDUSTRY

NOVUS RHT-AIR WIRELESS TRANSMITTERS OFFER LAB MONITORING SOLUTION



Process validation in the pharmaceutical industry is critical; physical or chemical changes in medications can result in the loss of their effectiveness. Hence, rigorous and adequate temperature and humidity control in pharmaceutical industry environments, such as laboratories and clean rooms of storage areas, is of great importance. A company located in Barueri, in the São Paulo metropolitan area, presented a challenge: implementing a monitoring system in its facilities without requiring rewiring or other changes in infrastructure. The main objective of the company was to obtain the release of new drug formula-

tions from the laboratory to production, which required approval from the regulatory agencies and necessitated that the assembled monitoring system be properly validated.

Each regulatory agency has its own set of rules, such as the [FDA 21 CFR Part 11](#), which provides for good practices during drug manufacturing. Among the requirements are the monitoring of ambient temperature and relative humidity used in storage and handling environments of drugs and vaccines, considering the requirements of each type of product. The data collected and recorded must be kept for up to five

and be available for consultation. With the recorded information, it is possible to trace batches of products handled by the laboratory, thus ensuring the manufacturer's quality assurance. This data must be stored in an unalterable format to prevent any tampering after the fact. The installation and operation of the system must be validated in a documented, systematic manner to ensure the integrity of the measurements and data throughout the process.

INSTALLATION

For the laboratory in Barueri, NOVUS came up with a turnkey solution that could fulfill



all customer needs: to set up a remote monitoring system without modifying the structure, products that guarantee reliable measurements, storage of data, compliance with regulatory requirements and process validation. The fact that only one supplier offered the whole solution was a key point in closing the deal since the company would buy not only the products but also the installation, calibration, and validation of the system. NOVUS, as an established instrumentation manufacturer, provided peace of mind to the customer, mainly because they had a reliable

source to turn to in the case of facility changes, new requirements, calibration, or repairs.

The project installed in Barueri's laboratory consists of four data acquisition panels, composed of NOVUS [FieldLoggers](#)- high performance, high-resolution data loggers - and [AirGate Modbus](#) receivers, which act as a connection interface between the data loggers and the wireless transmitters using the industry-standard Modbus RTU protocol. In addition, because of the size of the facility, the project has four repeater panels, also equipped with AirGate Modbus modules.

But the highlights of the installation are the 84 [RHT-Air](#) transmitters. A turn-key solution for measuring temperature and humidity over long distances, the RHT-Air allows the configuration and reading of the parameters via the wireless IEEE 802.15.4 protocol, over distances of up to 1 km, bringing practicality and efficiency to the application. Because it works without cables, it has simplified installation, eliminating the need for changes in the structure of the building, making it the ideal option for the Barueri laboratory. If there is a need to extend the network, simply attach the new sensor where necessary and configure it at a distance! Finally, RHT-Air operates on its own wireless network, without the need to use the company's IT infrastructure, allowing its stand-alone operation. The system employs the Novus NXperience Trust configuration and data collection software specially designed for the pharmaceutical, food and life science market segments that require a validatable solution. NXperience Trust complies with the requirements of FDA 21 CFR Part 11 with the ability to provide an electronic record of encrypted data, a strong authentication mechanism with password validation, and an application event log for traceability and audit trail. In addition, installation and operation qualification protocols are available separately.

BENEFITS

Since the system is validated within the standards, the application will already achieve payback when it passes its first audit. The main reason the customer chose NOVUS was the ability to obtain everything needed from the same supplier, gathering all the necessary aspects for the system's implementation, including ease of implementation, wireless technology and the flexibility of the solution to expand.

For more information on the [Novus RHT-Air](#), process validation in the pharmaceutical industry, or to find the ideal solution for your application-specific needs, contact a CAS DataLogger Application Specialist at **(800) 956-4437** or www.DataLoggerInc.com.