



PHARMACEUTICAL INDUSTRY

From Windows XP SCADA to 21 CFR Part 11 compliance: PIA modernizes Europharma/Gemphar monitoring with atvise®

Connected to a Unitronics PLC and 32 field sensors via OPC UA, atvise® gave Europharma/Gemphar web-based access, automated compliance reporting, and audit-trail traceability across its Bogotá pharmaceutical plant.

CUSTOMER:  **europharma**

PARTNER:  **PIA**

Executive Summary

Europharma/Gemphar, a pharmaceutical company based in Bogotá, Colombia, needed to replace a legacy SCADA system that had reached the end of its useful life, running on unsupported Windows XP hardware and accessible from a single physical workstation. Beyond the operational bottleneck, migrating to a web-based platform had been formally required by the IT department, and compliance with 21 CFR Part 11, the regulatory standard governing pharmaceutical manufacturing records and data integrity, was mandatory, not optional.

Solution

PIA implemented a web-based SCADA system using atvise®, connecting a Unitronics PLC and 32 field sensors via OPC UA to bring real-time monitoring, automated reporting, and full 21 CFR Part 11 compliance to Europharma/Gemphar's Bogotá plant.



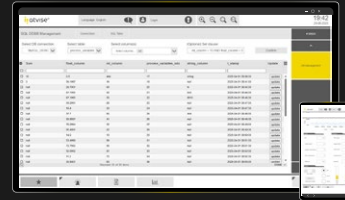
Client & Partner

The customer is Europharma/Gemphar, a pharmaceutical company based in Bogotá, Colombia. PIA (Proyectos de Ingeniería Aplicada S.A.S.), the system integrator that carried out the project, is a small Bogotá-based engineering firm whose founders bring 15 to 16 years of industry experience; the company itself has been operating for approximately eight years. Despite its size, PIA has built a track record working with large industrial clients, and at the time of this project was one of a small number of companies in Colombia with two years of dedicated development and training on the atvise® platform. PIA was already an established Vester partner, having worked across multiple clients in that capacity, and its knowledge of Colombian industry norms added further relevance to the project.

Objectives



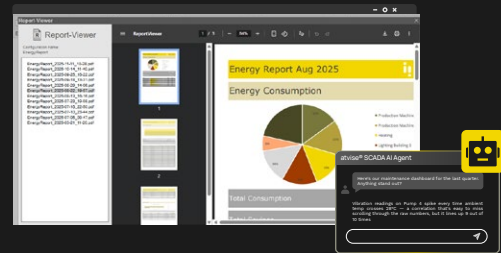
Replace the unsupported legacy SCADA and its outdated Windows XP hardware with an actively maintained platform.



Migrate to a web-based system accessible beyond a single workstation.



Achieve full compliance with 21 CFR Part 11 for pharmaceutical manufacturing records and data integrity.



Speed up report generation and make process data easier to visualize and interpret.

The Challenge

- Legacy SCADA no longer supported or receiving updates, running on Windows XP hardware that needed replacing.
- Access limited to a single physical workstation, creating an operational bottleneck.
- Report generation was slow and difficult to interpret visually.
- Web-based migration formally required by the IT department.
- 21 CFR Part 11 compliance non-negotiable for pharmaceutical manufacturing, and not yet met.

Results & Benefits

Web accessibility



The system can now be accessed from any device on the company's local network, removing the dependency on a single physical computer.

Faster, cleaner reporting



Report generation became significantly faster, with all data now compiled into a single consolidated PDF.

Improved visualizations



Process graphics and trend charts were upgraded visually, making data easier to read and act on.

Real-time trends in active use



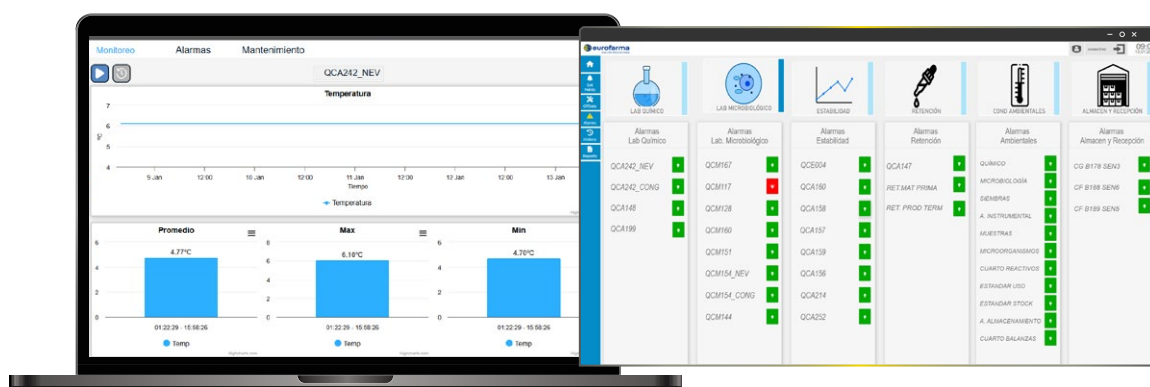
Trend monitoring existed before but was rarely used due to how difficult it was to access; with atvise®, it became a practical tool operators now use regularly.

Regulatory compliance



The system meets 21 CFR Part 11 requirements, including Audit Trail and calibration management directly from the platform.

The client's satisfaction with the outcome led to two concrete follow-on actions: Europharma expanded to a larger atvise® license, and contracted PIA for a second project on the same platform, a stability management system for pharmaceutical products.



Background

Three aspects of the collaboration with Vester were particularly relevant to the outcome. The proof of concept, built by Vester and presented by PIA to Europharma, was instrumental in winning the project, giving the client a concrete view of what the final solution could deliver. The 21 CFR Part 11 compliance document was prepared jointly during the proposal stage, helping address the client's regulatory concerns directly. And over the two years PIA has worked with the atvise® platform, ongoing technical support and training let PIA build deep platform expertise and deliver a higher-quality result to its end customer.

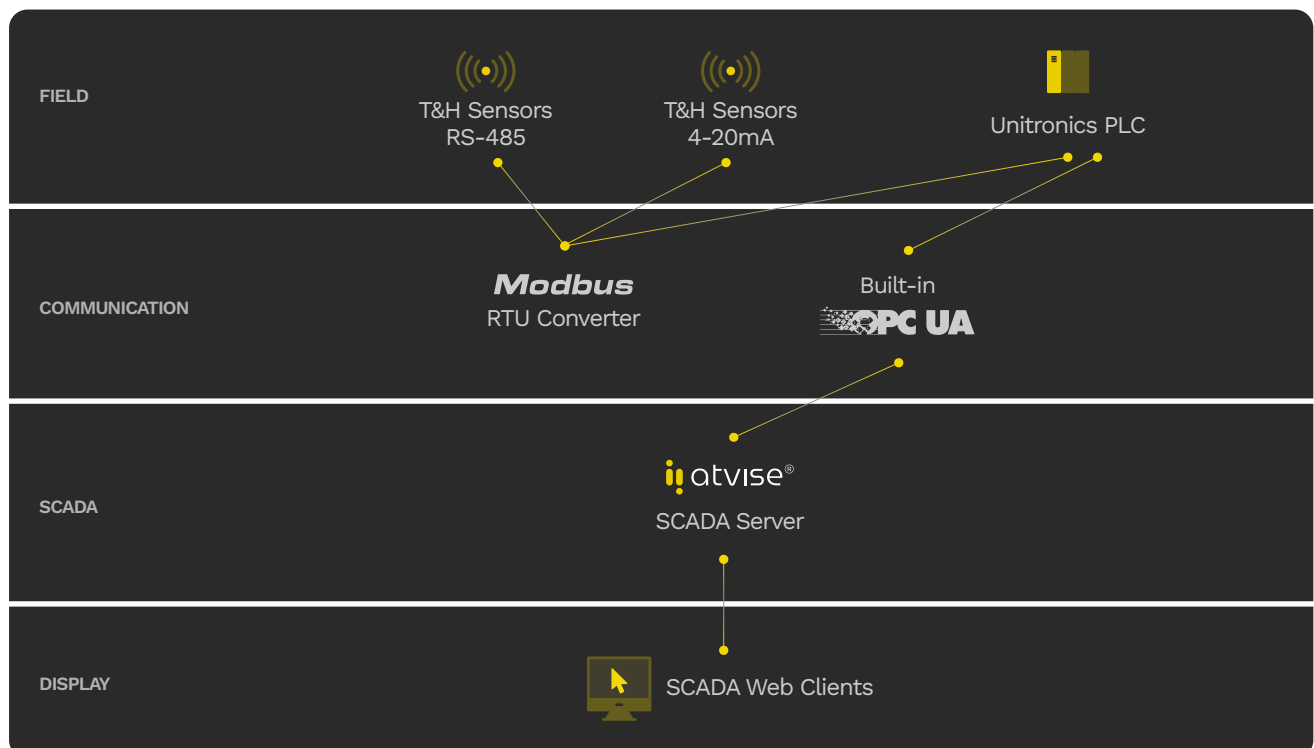
“The atvise® platform, combined with Vester's support at every stage, allowed us to deliver a solution that not only solved the client's technical problems but also met their regulatory requirements, and that trust translated directly into a second project.”

— Oscar Eduardo Sánchez, CEO and Owner, PIA

The Solution

PIA implemented a web-based SCADA system using atvise®, connected to a control panel with a Unitronics PLC linked to 32 field sensors of different types, including 4-20 mA and Modbus devices. Communication between the PLC and the atvise® SCADA was established via OPC UA, providing a reliable, standards-based data exchange layer.

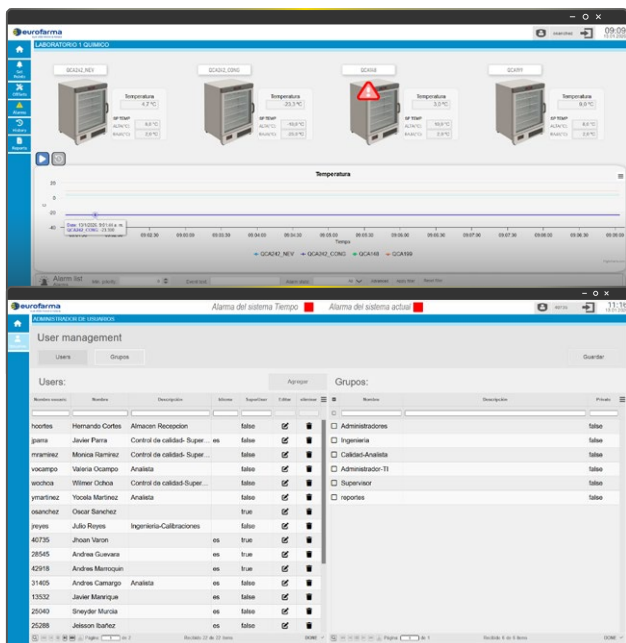
The atvise® SCADA platform was configured with process overview screens, alarm and event management with Audit Trail functionality, and real-time trend charts updated every minute. The system also enables report generation in PDF format, calibration management directly from the platform, and full compliance with the 21 CFR Part 11 regulatory standard. Once deployed, the system became accessible from any point within Europharma's local network, eliminating the single-workstation dependency that had constrained operations previously.



Level 0 field sensors (temperature and humidity) communicate via RS-485 or 4-20 mA analog signals, converted to Modbus RTU. These signals reach a Level 1 Unitronics PLC, which has a built-in OPC UA server. A Level 2 atvise® SCADA server connects to the PLC as an OPC UA client; from there, SCADA web clients can access the information via web services from any point on the network, at any level of the architecture.

Features used

- Web-based real-time monitoring
- Alarms dashboard
- Real-time trending
- 21 CFR Part 11 PDF report generation
- Alarm setpoints
- Instrument calibration



atvise® SCADA

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