

# Implementation of a BMS System in Clean Rooms for Medical **Devices Production**

A proactive approach to Out-of-Specification deviation prevention, critical process optimization, and regulatory compliance.

PARTNER:





## **Project**

Amid the growing demand for high-quality medical devices, Nextern, a leader in the medical device industry, expanded its operations in Costa Rica. As a crucial part of this process, it was essential to ensure compliance with strict environmental conditions in cleanrooms dedicated to the production of catheters and mechanical assemblies.

### Solution

The choice of a company capable of automating processes became essential for the success and sustainability of Nextern's operations in Costa Rica. Circuito Cinco, a renowned integrator in the field of automation and control, was contracted to develop and implement an advanced visualization system, using atvise® as its central SCADA system, integrated with an existing Mitsubishi PLC responsible for facility control.

#### Customer



Nextern is a leading company in the manufacturing of medical devices. Following its recent expansion in Costa Rica, it faces the critical challenge of meeting the growing demand for high-quality medical devices while ensuring compliance with strict environmental conditions in cleanrooms. It was at this crucial moment that Nextern decided to partner with Circuito Cinco.

### **Partner**



Circuito Cinco is a company with a strong track record and expertise in the industrial automation market and supply of electrical materials in Costa Rica. Their successful collaboration with Nextern in automating critical processes in the production of medical devices highlights their experience and ability to provide reliable solutions in demanding environments. This solidifies their position as a trusted strategic partner for industry-leading companies.





### Goals

- Visualizing Critical Variables: Establishing a monitoring and control system to visualize essential variables, such as temperature and pressure, ensuring the integrity of the production process.
- Scalable System: Implementing an adaptable solution that can grow with Nextern's needs, ensuring its effectiveness in a constantly evolving environment.
- **Compliance with Standards and Regulations:** Ensuring that operations comply with quality standards and applicable health regulations, supporting the reliability of the products.
- ! Continuous Improvement and Operational Efficiency: Using historical data to drive continuous improvements and optimize operational efficiency, reducing downtime and making data-driven decisions to maximize productivity.

## Challenges

- Modular and Scalable System: Developing a system adaptable to Nextern's future needs.
- Integration with Existing Equipment and Sensors: Achieving seamless integration with existing systems, including a Mitsubishi IQ-F series PLC and Modbus protocol.
- **Effective Alerts and Notifications:** Implementing an alert mechanism that detects and notifies deviations in real-time.
- Data Management and Security: Facing data management and information security effectively.





#### Results

The implementation of this solution for Nextern has been a pivotal step in their pursuit of excellence and meeting the growing demand for high-quality medical devices. Key outcomes of this implementation include:

- High-Security Monitoring System: The new high-security visualization system provides immediate notifications for alerts and alarms, ensuring the quality and protection of production.
- Improved Predictive Maintenance: Thanks to the implemented solution, Nextern can carry out predictive maintenance more effectively, reducing downtime and optimizing resources.
- Comprehensive and Reliable Data History:
  A complete and reliable data history has been generated, meeting audit requirements and enabling continuous improvement. This aids data-driven decision-making and optimizes production processes.

In summary, the implementation of this solution has elevated the quality and efficiency of Nextern's operations, strengthening the company's competitiveness and commitment to excellence in the medical devices market.

"Due to the excellent results achieved, there is consideration for expanding the implementation to other cleanrooms within the company."

- Ernaldo Ruiz, Project Manager at Circuito Cinco.

## **Background**

Continuous increase in demand for medical devices in the region, driven by the growing need for excellence in healthcare, marked a milestone in the evolution of Nextern. This leader in the medical devices industry recognized the urgent need to establish a cleanroom with rigorously controlled operating conditions to ensure the quality of its products.

Before undertaking this challenge, Nextern faced a critical gap in its production process. The absence of historical data and the lack of real-time alert systems represented a significant obstacle. The search for a solution was not limited to addressing this problem but also finding a strategic partnership that would enable them to succeed in an ever-evolving market.

"Information obtained in the implementation of the BMS is vital for the validation and auditing process of Nextern. With atvise, the need for obtaining reliable and real data is covered."

- Ernaldo Ruiz, Project Manager at Circuito Cinco.





## Solution

Collaboration between Nextern and Circuito 5 culminated in the implementation of a state-of-the-art Building Management System (BMS) focused on cleanrooms for medical devices production. This cutting-edge solution harnesses the power of the atvise® SCADA system, integrated with a Mitsubishi PLC from the IQ-F series. The system communicated through the Modbus protocol, facilitating seamless integration of the existing equipment and sensors in the facility.

The BMS was designed from the ground up to be modular and scalable, allowing future expansions and adaptations as Nextern's needs evolve. Technical support and ongoing training ensured a swift and efficient implementation.

"The ease of configuration, versatility, along with a competitive price and efficient local technical support, allowed for a swift and effective implementation of the redundancy system with atvise"".

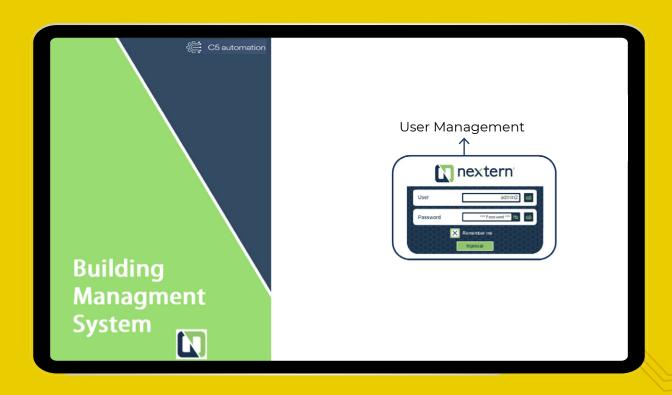
- Ernaldo Ruiz, Project Manager at Circuito Cinco.

One of the most highlighted features of the system is its ability to monitor various critical variables in real-time, such as temperature, relative humidity, differential pressure, the frequency of air conditioning handlers, and electrical variables of the condenser. These data are crucial not only for compliance with strict industry regulations but also for the quality and efficiency of the production process itself.

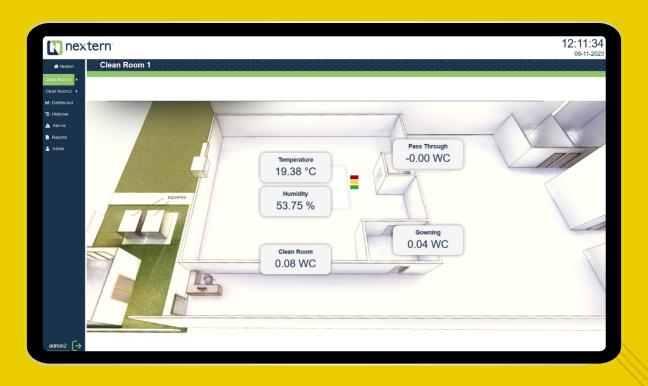
The choice of atvise® as the SCADA system offered additional advantages, such as advanced report generation and an unlimited historian, enabling Nextern to maintain detailed records for audits and future data analysis. Additionally, the atvise® platform comes with email notification features for alerts and critical events, allowing for quick interventions to prevent deviations outside specifications.

- "The ability to monitor the room and control alarms gives us the peace of mind to take immediate action when needed, and it also allows us to maintain a historical record of data that has been crucial for our operations".
- Ernaldo Ruiz, Project Manager at Circuito Cinco.

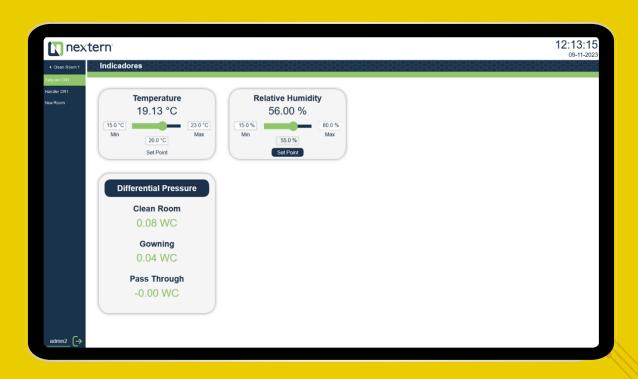




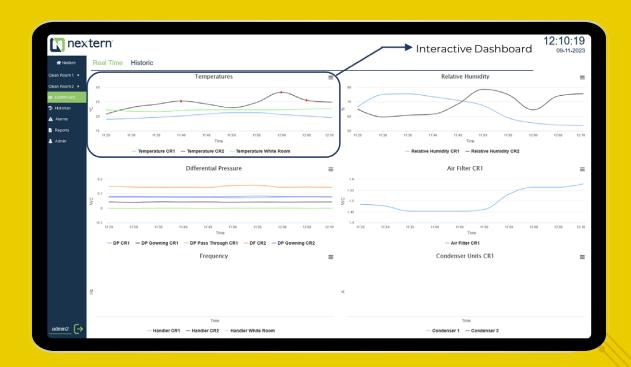














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