CASE STUDY

Pharmaceutical Plant Achieves Precision with Niagara Framework and Advanced Analytics

INTRODUCTION

ISTEM Medical is a forward-thinking manufacturer specializing in medical devices, healthcare solutions, and biotechnology products. With a state-of-the-art production facility that includes 2,000 square meters of clean room space, ISTEM Medical exports over 40 million products to 60 countries annually. The company's commitment to quality and innovation is at the forefront of their operations, driving them to integrate advanced analytics and e-signature solutions into their manufacturing environments, ensuring strict compliance and precision in every step of production.

AT A GLANCE

Project Type: New Software Install
Client: ISTEM Medical
Niagara Partner: Ontrol
Property: Pharmaceutical Plant
Date: 2023
Key Technologies: Niagara Framework, Niagara Analytics, E-Signature

UNIQUE REQUIREMENTS

ISTEM Medical faced a complex set of operational demands that extended well beyond traditional HVAC controls. For a company dedicated to exceeding the highest regulatory and quality standards, maintaining precise control over environmental conditions such as temperature, humidity, and pressure was critical. These conditions had to be consistently monitored and meticulously documented to meet the rigorous demands of regulatory audits.

In addition to environmental controls, ISTEM Medical required unalterable, date- and time-stamped logs that could not only track real-time conditions but also provide historical data for deep analysis. Such data is essential for predicting the impact of conditions during the storage and transport of sensitive medical products.

Recognizing the need for an advanced solution, ISTEM Medical selected the Niagara Framework. Its comprehensive capabilities allowed them to address all operational requirements without the need for additional systems or software. The framework's local support and extensive integration potential further solidified Niagara as the ideal solution for their needs.

"The Niagara Framework has significantly streamlined our operations. We can now swiftly submit report requests to the Ministry and other regulatory institutions, complete with pre-approved electronic signatures, ensuring full compliance.

The system's intuitive interface and visually appealing graphics demonstrate its user-centric design, making it exceptionally convenient for our 24/7 operations. Its ease of use allows us to focus more on maintaining optimal conditions rather than managing complex controls."

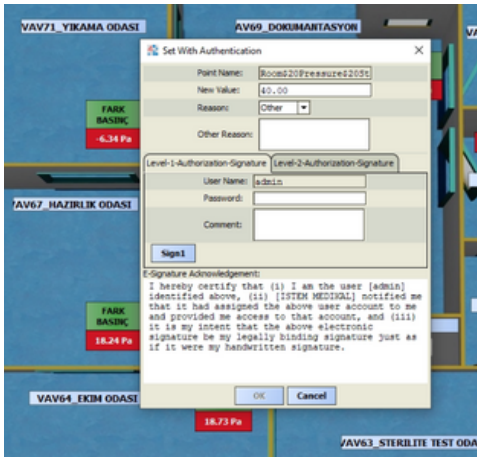
Soner Kaya

ISTEM Medical Operations and Maintenance Manager

E-SIGNATURE APPLICATION

A critical aspect of the project was the implementation of Niagara's E-Signature feature, which plays a vital role in meeting regulatory audit requirements. This feature enables authorized personnel to make manual changes or overrides, but with an added layer of security — managerial approval. Every modification is recorded with e-signature authentication, reason for change, and accurate time and date stamps, ensuring that all logs are unalterable.

By integrating the E-Signature feature into ISTEM Medical's standard operating procedures, the company now confidently maintains accurate records, vital for regulatory audits and product quality assurance.



ADVANCED ANALYTICS

The pharmaceutical industry demands more than simple trend logs and alarms — comprehensive data analysis is crucial. Niagara's Analytics Framework provided the tools needed to delve into historical data, enabling ISTEM Medical to verify and document critical environmental conditions.

One such requirement was the calculation of Mean Kinetic Temperature (MKT), a key parameter used to assess the impact of temperature fluctuations on perishable pharmaceutical products.

$$T_k = \frac{\frac{\Delta H}{R}}{-\ln\left(\frac{t_1 e^{-\frac{\Delta H}{RT_1}} + t_2 e^{-\frac{\Delta H}{RT_2}} + \cdots + t_n e^{-\frac{\Delta H}{RT_n}}}{t_1 + t_2 + \cdots + t_n}\right)}$$

This calculation involves a complex set of computations on historical data to ensure accurate results. Niagara's intuitive programming environment, with its use of function blocks, made it possible to create and implement these complex algorithms efficiently. Moreover, the framework's advanced graphics capabilities allowed for easy visualization and reporting of the data, making it accessible to ISTEM Medical's operators.

BRINGING IT TOGETHER

The successful implementation of the Niagara Framework at ISTEM Medical was carried out by Energon, a trusted partner of Ontrol, known for its extensive local engineering expertise. Energon's experience, coupled with technical support from Ontrol at every phase of the project, ensured seamless integration and ongoing reliable operation of the system.

Tridium's Niagara Framework, renowned for its open architecture and scalability, provided ISTEM Medical with a future-proof solution capable of evolving alongside their needs. The flexibility and adaptability of Niagara, combined with the deep industry knowledge of both Energon and Ontrol, allowed ISTEM Medical to fully leverage the power of integrated systems to meet stringent regulatory requirements while optimizing operational efficiency. This collaboration exemplifies the strength of Tridium's global ecosystem in delivering customized, high-performance automation solutions.

ABOUT ONTROL

Ontrol, headquartered in Turkey, boasts a global presence and has been a trusted leader in designing and manufacturing automation and control products for HVAC applications for over 60 years. Collaborating with renowned global partners in the smart buildings sector, Ontrol delivers integrated building management solutions to resellers, systems partners, contractors, developers, and building owners worldwide. As pioneers in adopting Tridium's Niagara Framework®, Ontrol empowers intelligent and efficient operations in buildings, data centers, manufacturing systems, smart cities, and beyond. Additional information about Ontrol is available at www.ontrol.com

TRIDIUM

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