Improving Operations & Cyber Defense at a Leading Pharmaceutical Company in India

Any company in a regulated industry like pharmaceuticals must meet stringent compliance and security requirements. 'What is not documented, is not done,' is just one of the maxims that guide every step of production in a pharma company. As is true for any industrial processing environment, factors like ambient temperature, humidity and vibration can impact outcomes, so environmental services need to be delivered with attention to reliability, quality and documentation commensurate to pharma standards. For all these reasons and more, a building management system (BMS) designed to serve in a pharmaceutical production facility presents a unique set of challenges beyond the scope of any standard-issue BMS. Conexao Technology Solutions deployed its Niagara Framework®-based O-Insights™ BMS at one of India's leading pharmaceutical companies, addressing these operational challenges and helping the facility stay compliant with regulations set by food and drug authorities around the world.

CHALLENGE

When Conexao was brought in to bid on this BMS upgrade project, the customer had the following issues with the existing BMS:

▶ Security was suboptimal. Pharmaceutical companies view data leakage as a major threat. Getting a drug to market is a long, costly, and time-competitive pursuit, and theft of intellectual property (IP) along the way is a concern. The existing BMS was transferring operational data over unsecured BACnet protocol, which presented an unacceptable vulnerability. It also did not enforce strong user authentication and did not offer SSL or 802.1x support. Thus, it did not meet basic enterprise-grade cybersecurity standards.

▶ The users and number of concurrent users in the system were limited, and adding new users involved new licensing at every step.

▶ There was little support for various industry standard protocols.

▶ The reporting function was basic and offered little flexibility to the client. There was no easy way to customize templates, and even minor changes in the formatting of reports necessitated the intervention of experts.

▶ An unwieldy alarm management process required that each alarm be individually acknowledged with multiple steps. The BMS operator had no way of knowing how long the alarm had stayed active.

▶ The software was complex and not well matched to meet the stringent compliance and security requirements of the pharmaceutical industry.

"O-Insights was able to resolve operational challenges for this pharmaceutical leader, who puts safety, rigorous standards and efficiency above all. The BMS/EMS capabilities of Niagara Framework® are unparalleled and this prompted us to build O-Insights on this foundation."

Amit Dorugade
Product Manager
O-Insights

FAST FACTS

Authorized Niagara Reseller Partner:

Project Type: Building Management System upgrade to support Energy Management System custom-configured for pharmaceutical production.

Project area: +95K square feet of climate-controlled area

Project Scope: Services under Niagara management include HVAC (air handling units, dehumidifiers, VFD's, heaters, room monitoring sensors, VCD's and more); Energy; and Room Display Units. Over 700 assets with 3000+ points integrated.

Key Technologies: Niagara Framework for data integration and normalization; O-Insights Agile Workspace for bespoke visualizations of data; SignFlo for customized workflows for e-signing reports; BACnet/SC for secure communications.

O-Insights for Niagara is a powerful visualization, reporting, and analytics tool that has been developed to fit natively within a Niagara Framework®-based BMS.

SOLUTION

The O-Insights team started by integrating operational data across this pharma customer's facilities. Over 700 equipment assets with 3000+ points of control needed to be tied into a unified Niagara network. This work required third-party integrations over proprietary protocols, as well as via open protocols like OPC UA and Modbus. The switch to the Niagara-based BMS offered:

▶ Freedom from the arbitrary and profligate licensing restrictions imposed by the previous, dated BMS solution. The customer could create an unlimited number of user profiles and sessions.

▶ Comprehensive standard security including enterprise- level authentication schemes such as LDAP, SAML and Kerberos.

▶ Many of the industry standard protocols are supported out of the box, including BACnet, Modbus, OPC, and LON. Other proprietary protocols such as C-BUS, N2-BUS are also supported.

On top of the Niagara BMS, the project team overlaid O-Insights Workspace, Reporting, and SignFlo delivering the following additional functionality:

▶ Native-Niagara widget-based agile workspace providing dashboard views of operational data in near real-time. This workspace is designed to present customized views to various stakeholders, from facility operators to top managers. It equips the client with various report types and great flexibility in terms of schedulable and automated design.

▶ Alarm management with O-Insights Alarm Console for Niagara takes the already excellent alarm management in Niagara to the next level with various unique features that make alarm management effortless.

▶ Tridium Professional Services-developed Niagara 4 E-Signature Application (ESIGN) to enable paperless workflows.

SIGNING OF PHARMA WORKFLOWS

Pharmaceutical manufacturers need to optimize their workflows for frequent regulatory audits, designed to ensure the reliability, integrity, and veracity of data collected during the research, development, manufacturing, and testing of drugs and medical devices. The International Organization for Standardization (ISO) sets guidelines for Good Manufacturing Practice (GMP) and Good Documentation Practice (GDP). O-Insights SignFlo tool enables this customer to minimize any risk of failing an audit by incorporating the Niagara 4 E-Signature Application developed by Tridium Professional Services. O-Insights SignFlo with Niagara 4 ESIGN facilitates entirely automated and paperless workflows. It enables hassle-free documentation for the facility in line with the customer's vision of digital transformation.

With this combination, O-Insights users can create and manage controlled audit logs to ensure that the data is accurate, time and date stamped, and unalterable. When manual changes and overrides are required, the Niagara 4 E-signature Application can ensure the changes and overrides are made by authorized personnel, approved by managers, and documented in audit files, thereby complying with GDP.
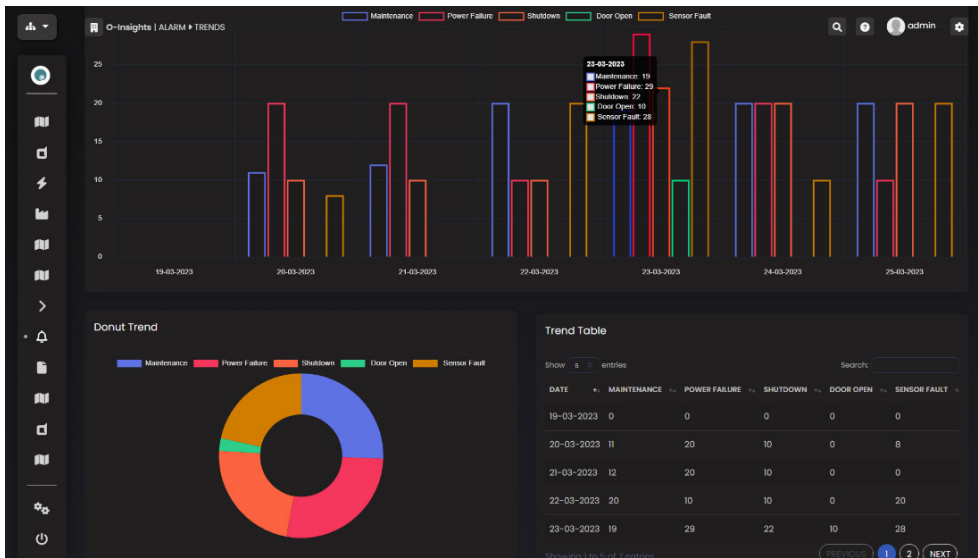
O-Insights Alarm solution elevates the user experience by delivering on-the-fly alarm analytics, including alarm count, duration, and reason along with escalation levels, user notification, raising tickets, and more.

RESULTS

The whole BMS-driven Energy Management and Reporting solution was made secure and seamless to the client requirements with enhanced feature/functions including:

▶ Data is now being transferred over the secure BACnet/SC protocol, such that the client can login only if certificates are available.

▶ Controller-level login with E-Signature is mandated.

▶ Powered by SignFlo, the whole process of acquiring signed reports with various workflows and meeting all the compliance requirements is seamlessly performed.

▶ The latest cyber defense standards are supported, such as TLS 1.3 for encrypted communications and LDAP & SAML multi-factor authentication. For a complete list, see the Niagara 4 IT Primer here.

▶ The Backfilling function ensures that no data is lost, even when the communication between the controller and BMS is lost.

▶ The Reporting function enables custom report templates and meets various report type requirements.

▶ Any changes to configurations can be made with zero downtime, on the fly.

▶ Alarm acknowledgement can now be done in batch, minimizing tedium and potential for human error.

▶ Department-specific alarm consoles provide:
  • Flexibility in alarm management with ability to add reasons based on alarm class.
  • Alarm notifications that help ensure that no alarms are missed.
  • Alarm instructions help to remediate issues with specific instructions for users and operators.

▶ Realtime duration of the alarms are displayed in the console. When the GMP parameters approach the alarm limit, the colour changes instantly so that it can be promptly attended to before going to the alarm state.

▶ Alarm data can be holistically visualized via an Alarm Trends view. Here insights into alarm data are captured through various charts.

ABOUT CONEXAO TECHNOLOGY SOLUTIONS

The team at Conexao Technology Solutions (CTS) is propelled by years of experience in developing cutting-edge automation, integration, and software solutions. It is the developer of O-Insights for Niagara, a comprehensive suite of software solutions that seamlessly integrates with Niagara to deliver energy management, safety and compliance, energy forecasting and control, AI-based business intelligence, and a lot more. CTS's native Niagara approach ensures that every aspect of a building's lifecycle is meticulously monitored and optimized, all within the Niagara platform. Learn more about CTS at www.conexaotechsolutions.com.

ABOUT TRIDIUM

Tridium is a world leader in open protocol business application frameworks — advancing truly open environments that harness the power of the Internet of Things. Tridium's Niagara products enable diverse monitoring, control and automation systems to communicate and collaborate in buildings, data centers, manufacturing systems, smart cities and more. Tridium's Niagara products are at the core of smarter, safer and more efficient enterprises and communities — bringing intelligence and connectivity to the network edge and back. Additional information about Tridium is available at www.tridium.com.

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