Manufacturing Plant for Multinational Pharmaceutical Company Implements AutoSave for Configuration Management and Regulatory Compliance

Application Story: Life Sciences

Challenge:

The plant, manufacturing various pharmaceutical forms including tables, syringes, vials, nasal sprays and oral solids, realized it was not effectively managing the program configurations of hundreds PLCs of varying types and ages. The original change management process heavily relied on technical personnel to follow operating procedures to the letter in a highly regulated environment. The plant needed a change management solution that would minimize human error, increase efficiency in terms of technical support and maintenance, and comply with strict regulations.

AutoSave's workflow approval routing and electronic signature functionality ensure that processes have not been altered without approval or documentation (supporting compliance with government regulations such as FDA 21 CFR Part 11).

Solution:

In researching different solutions, the plant discovered there were generic off-the-shelf configuration management solutions available on the market but that these are highly intrusive and poorly suited to production environments. They found that the drawbacks of these solutions are particularly apparent in regimented environments.

The plant ultimately selected the AutoSave Change Management solution as it not only provides a centralized system that manages changes to program logic for automated controls programs and devices but also an approval and audit infrastructure that ensures compliance with FDA regulations and international pharmacopoeia standards.

Results:

MDT AutoSave serves as the centralized repository for all of the software versions of every PLC present in the plant's system, both those connected over the network and standalone PLCs. Now, if a device fails, rollback and recovery data is immediately accessible. Additionally, with AutoSave's comparison feature, designated personnel are notified when the program running in the device does not match the program copy on file, protecting the plant's personnel, processes and products. AutoSave's audit trail and approval support, combined with electronic approval and workflow approval, also help the plant comply with regulatory rules.

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Automation Change Management