

PROJECT PROFILE

Modernizing data management for CGMP compliance AMPAC Fine Chemicals

Client background

AMPAC Fine Chemicals is a custom manufacturer of active pharmaceutical ingredients (APIs) and registered intermediates for customers in the pharmaceutical industry. Their facility in Sacramento, California, specializes in process development, scale-up, and CGMPcompliant (Current Good Manufacturing Practice) production from kilogram to multi-ton quantities. They entrusted Enterprise Automation in 2022 to design and implement a historian.

Project background

AMPAC Fine Chemicals utilizes a historian to store and validate process data. AMPAC recognized the need to modernize and update its data historian and validation processes. They sought an upgraded historian that would improve efficiency, connect all their Citect clusters, and ensure data validation. To achieve this goal, they implemented two new historian VMs and connected them to their existing Citect sites. Enterprise Automation completed the system's upgrade, implementation, testing, and validation.

EA solution

Our upgrades to AMPAC's AVEVA Historian and Citect systems resulted in more efficient and validated data access with improved redundancy and flexibility. We worked with AMPAC to build two VMs to store historical and alarm data redundantly in multiple locations in case of failure. All eight Citect clusters were connected to these machines to ensure data was connected, streamlined, and efficient.

The existing historian was not sized or licensed for the entire data they possessed, so we built a new system that would store ten years' worth of past data. Unlike the previous system, AVEVA Historian allowed flexibility for the end user to historicize selected data as opposed to only historizing trend tags.

We performed validation to provide evidence that the new system meets the client's needs and confirmed the system met CGMP requirements and guidelines. The communication between both teams went smoothly throughout, as we worked closely with AMPAC's engineering, IT, and quality assurance departments. This close collaboration prevented data loss before installation, and enabled installation to be completed without any downtime or impact on production.

Project Manager



Project Technical Lead



Key Insights:

- · No downtime or cessation of production during Historian implementation
- Connected 8 Citect Clusters for streamlined data communication and lost no data during installation
- Improved system security with installation of 2 VMs

Key Technologies:

- AVEVA Historian 2023
- Citect SCADA Connector