ATS CUSTOMER STORY

Centralised DAS Validation Success in a Pharmaceutical Company

Industry
Pharmaceutical

About Customer
Our customer is a pharmaceutical company that specializes in the development, manufacturing, and marketing of a wide range of pharmaceutical products. It operates globally and focuses on both generic and branded pharmaceuticals, including various dosage forms such as tablets, capsules, injectables, and topical solutions. The company also has a presence in several therapeutic areas including anti-infectives, cardiovascular, central nervous system, and oncology, among others. It is known for its commitment to quality and innovation in the pharmaceutical industry.

Location
Worldwide

Challenge

Customer wanted us to do validation of Centralized Data Acquisition System for Formulation Manufacturing Equipment's as per EU Annex 11, FDA 21CFR Part 11 and GAMP 5 Standards.

Approach

- Preparation and execution of the deliverables
- Project Validation Plan
- Initial risk assessment (GXP assessment) & Functional Design Specification (FDS)
- Functional Risk Assessment
- Migration Plan and System Release Certificate

Solution

- Configuration Specification for tags and reports
- Installation Qualification protocol, SAT, Operational and Performance Qualification Protocol
- We follow GAMP5 guidelines to prepare the deliverables (Requirement Traceability Matrix, Validation Summary Report)

Results

- Reduced Inspection time & frequency, thereby reducing waste and enhancing productivity
- Enabled customer to meet the compliance requirements