



FULFILLING DATA INTEGRITY GAPS WITH DIGITALIZATION



Data integrity, a crucial aspect of Life Science manufacturing, has been a driving factor for many companies to upgrade their existing systems. Leaders in the industry are upgrading facilities and improving systems in an effort to go paperless and reduce scenarios that are prone to human error.

THE PROBLEM



This large, US-based pharmaceutical company's production facility located in Singapore, enlisted RoviSys to upgrade a facility with parts washer skid systems that did not comply with new data integrity requirements. Additionally, the cycle report analysis process at this facility relied entirely on manual procedures, where an operator manually compared printed data logs against acceptance criteria for quality assurance. A combination of issues that negatively impacts production.

ROVISYS

The client's original equipment manufacturer (OEM) system was more than 20 years old. It was counterintuitive to use, lacking sufficient provisions for traceability of individual user actions, and it did not store any historical data. Additionally, there was no P&ID display available to facilitate the visualization of instrument states within the system. This absence of vital information created a significant gap in the data integrity requirements and resulted in prolonged downtime during troubleshooting.

Based on a relationship that began in 2010, and has grown to over 75,000 engineering hours, SGD \$9M in value-added project work and successful project execution, RoviSys was an ideal choice as systems integrator partner for this effort. Additionally, as a Siemens Automation Solution Partner, RoviSys has proven success integrating, supporting and migrating Siemens and predecessor systems since the mid-1990s globally, and in Asia since 2011.



THE SOLUTION

After carefully considering the challenges, RoviSys proposed and delivered a solution that involved upgrading the human-machine interface (HMI) to an Industrial PC (IPC) with WinCC, along with the integration of Siemens premium add-ons: PM-Control and PM-Quality. The IPC was capable of connecting to the client's network, allowing for user access integration with Active Directory through SIMATIC Logon. WinCC offered an intuitive user interface with a detailed P&ID display, enabling the visualization of system instruments. The archiving functionality in WinCC also facilitated the retrieval of historical data on the HMI. Furthermore, the audit trail functionality ensured traceability of each user's actions.

RoviSys conducted an in-depth analysis of the existing PLC program to identify how the Siemens add-ons could be seamlessly integrated to automate the customized cycle reports. This integration allowed for the accurate capturing and reporting of critical parameter information during each phase of the cycle, which was essential for QA's assessment. Customized interface blocks with PM-Control enabled the

definition of different phases and recipe management. Through scripting in PM-Quality, customized reporting of critical cycle parameters was achieved. The report was populated with cycle data in the client's preferred format in real-time throughout the cycle. Additionally, physical reports were automatically generated at the end of each cycle, and past reports could be accessed on the HMI.



THE RESULT

The upgrade propelled the client further along their digitalization journey, adding functionalities that fulfilled data integrity requirements, provided an audit trail, and enabled user access controls that were not available with the legacy skid system. The inclusion of cycle reports eliminated the need for manual comparison of printed data logs after each cycle, enabling site supervisors to make quick, informed decisions in the event of a potential failed cycle.

Following the upgrade of one skid system, the client approached RoviSys to implement similar solutions for two remaining parts washer skids within the facility. Additionally, they sought assistance with automating cycle reports for other skid systems as well.

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