

Project Execution & Validation

Project #1 – Project #14.

Project #1

Project Value \$ 102,500

Batch System 21 CFR Part 11 Remediation: A major pharmaceutical company completed the gap analysis and remediation plan for their site-wide automated batching system. At that point, MAVERICK was contracted to complete the remediation and subsequent revalidation of the systems. The project included documentation, development, testing and validation per cGMP and GAMP (Good Automated Manufacturing Practice).

The primary user requirements of this project included the following: implement add-on software for an audit trail of SQL databases; modify existing system to secure batch report files from modification; modify existing system to monitor electronic copying and unauthorized system access; implement improved routing and consolidation of process data; create disaster recovery and security procedures; archive system recipes in an un-editable format; define job descriptions for system users; and implement full system security to ensure system entries and modification can be readily attributed to the correct user. This project was funded to satisfy an FDA compliance issue, and therefore no specific business case (ROI) for the project was documented.

MAVERICK's scope included site survey, user requirements, functional specification (including risk assessment), system architecture development, PLC/HMI/Batch modifications, SOP updates and SAT/IOQ development/execution. The installation included InTouch, InBatch, InSQL, MSSQL, Allen-Bradley PLCs, Lumigent Integra and Tripwire.

MAVERICK Technologies and the client worked closely together during the course of the project. The overall project timeline was compressed by following MAVERICK's Project Execution Methodology.

Project #2

Project Value \$ 90,000

Equipment Systems 21 CFR Part 11 Remediation: As a second phase of the Batch System Remediation (described above), a major pharmaceutical company completed the gap analysis and remediation plan for their site-wide miscellaneous systems including utilities, autoclaves, vial sterilizer and a Filler/ Stopper Statistical PC. At that point, MAVERICK was contracted to complete the remediation and subsequent revalidation of the systems. The project included documentation, development, testing and validation per cGMP and GAMP (Good Automated Manufacturing Practice).

The primary user requirements of this project included the following: implement add-on software for an audit trail of SQL databases; modify existing system to secure batch report files from modification; modify existing system to monitor electronic copying and unauthorized system access; implement improved routing and consolidation of process data; create disaster recovery and security procedures; archive system recipes in an un-editable format; define job descriptions for system users; and implement full system security to ensure system entries and modification can be readily attributed to the correct user. This project was funded to satisfy an FDA compliance issue, and therefore no specific business case (ROI) for the project was documented.

MAVERICK's scope included site survey, user requirements, functional specification (including risk assessment), system architecture development, PLC/HMI/Batch modifications, SOP updates and SAT/IOQ development/execution. The installation included InTouch, InBatch, InSQL, MSSQL, Allen-Bradley PLCs, Lumigent Integra and Tripwire.

MAVERICK Technologies and the client worked closely together during the course of the project. The overall project timeline was compressed by following MAVERICK's Project Execution Methodology.

Project #3

Project Value \$ 250,000

SCADA/SPC Implementation: A pharmaceutical company implemented a SCADA (Supervisory Control and Data Acquisition) and SPC (Statistical Process Control) for their Sterile Filling/Packaging and Plastics departments. The project included documentation, development, testing and validation per cGMP and GAMP (Good Automated Manufacturing Practice).

The primary user requirements of this project include the following: perform long term analysis of all product defects; provide an interface to monitor equipment status, alarms, downtime, etc. from a single location; replace handwritten QC reports (torque tests, visual inspections, etc.) with electronic data entry and reporting (21 CFR Part 11 compliant); provide storage and printing of batch and shift reports; pass SPC, QC and other batch and/or shift information directly to SAP without operator intervention; allow the analysis of data to generate trends and other SPC information; allow data gathered to be exported for offline analysis; establish a modular system for future expansions and deployments; and provide KPI data in a consistent manner. The business case for this project was based on the following: reduction of rework through immediate, automatic response to defects; reduction of waste and increased yield through supervisor adjustments of the process to new setpoints determined by historical analysis; identification of process bottlenecks in an effort to justify equipment maintenance, modifications and/or replacement; reduction of production manpower requirements for supervision and operation of the system; and reduction of quality assurance manpower requirements for manual product inspections.

MAVERICK's scope included site survey, functional specification, system architecture development, PLC/HMI/SPC configuration, FAT, SAT, operator training and IOQ development/execution. The installation included a new system consisting of ControlLogix, RSView, WinSPC, MS SQL and custom VB scripts to tie into the existing equipment PLCs.

MAVERICK Technologies and the client worked closely together in the client offices and MAVERICK's office during the course of the project. The overall project timeline was compressed by following MAVERICK's Project Execution Methodology.

Project #4

Project Value \$ 2,250,000

Air Separation Unit Upgrades: A major industrial gas supplier was required by the FDA to upgrade the control systems at their air separation units that provide medical grade gases. The projects required a fully documented configuration per current Good Manufacturing Practices (cGMP) that could then be validated for FDA compliance. In most cases, the owner decided to completely retrofit the control system at eight (8) of their plants.

MAVERICK's scope included site surveys, P&ID development, system architecture development, electrical engineering and design, panel design, control system and HMI configuration. The typical installation was approximately 750 I/O and included a Siemens Moore APACS DCS and Wonderware Factory Suite 7.1 HMI. The new configurations were performed using a detailed control system specification and subjected to documented testing at staging, customer witnessed factory acceptance testing (FAT) and site acceptance testing (SAT) to assure compliance to specification.

MAVERICK Technologies and the client worked closely together in the client site and MAVERICK's office during the course of the project. Shutdowns of the units were scheduled to maximize safety to the employees, minimize downtime and ensure all installation tasks were completed and the changes were thoroughly tested.

Project #5

Project Value \$ 300,000

Customer Site Support - DCS Server Upgrade and New Product: MAVERICK has provided on-site technical support for a pharmaceutical company for several months providing a variety of services. The project included documentation, development, testing and validation per cGMP and GAMP (Good Automated Manufacturing Practice)

MAVERICK's scope included gathering and analyzing Siemens Moore APS and APACS DCS data to help facilitate the closures of discrepancies and contaminations. UNIX TCL scripts were developed to streamline the Siemens Moore APS DCS data gathering process. The DCS server upgrade project included writing design documents for the new servers and systems, loading the new Compaq servers with the OS and Siemens Moore APS software, verifying the functionality of the new servers, and documenting and redesigning the user developed UNIX scripts for cGMP validation. The project included documenting the project design and redesigning existing Siemens Moore Direktor recipes for a new product.

MAVERICK Technologies and the client worked closely together in the client offices during the course of the project.

Project #6

Project Value \$ 100,000

Service Agreements: MAVERICK has performed a variety of service agreements for various biotech and pharmaceutical companies. These service calls include troubleshooting, change management, corrections and documentation to ensure that all modifications were made per cGMP and GAMP (Good Automated Manufacturing Practice). The typical installations included InTouch, InBatch, InSQL, Allen-Bradley PLCs, Intellution iFix, DVT vision systems and more.

MAVERICK Technologies and the client worked closely together in the client offices during the course of these projects. Shutdowns of the units were scheduled to maximize safety to the employees, minimize downtime and ensure all installation tasks were completed and the changes were thoroughly tested.

Project #7

Project Value \$ 35,000

Heat Sealer Supervisory System Project and DVT Vision System Project: A pharmaceutical company implemented two separate projects a Heat Sealer machine and a DVT Vision System. These projects included documentation, development, panel fabrication and testing per cGMP and GAMP (Good Automated Manufacturing Practice). Both projects were implemented to reduce the involvement of the local operators.

MAVERICK's scope included site survey, functional specification, system architecture development, PLC configuration, panel design/fabrication, SAT development/execution and operator training. The installation included a new system consisting of Allen-Bradley SLC and MicroLogix PLCs.

MAVERICK Technologies and the client worked closely together in the client offices and MAVERICK's office during the course of the project. The overall project timeline was compressed by following MAVERICK's Project Execution Methodology.

Project #8

Project Value \$ 35,000

Equipment Systems 21 CFR Part 11 Remediation: A major pharmaceutical company completed the gap analysis and remediation plan for their site-wide miscellaneous systems. At that point, MAVERICK was contracted to complete the remediation and subsequent revalidation of the systems. The project included documentation, development, testing and validation per cGMP and GAMP (Good Automated Manufacturing Practice).

MAVERICK's scope included site survey, SOP updates and Software Test Plan development/execution.

MAVERICK Technologies and the client worked closely together during the course of the project. The overall project timeline was compressed by following MAVERICK's Project Execution Methodology.

Project #9

Project Value \$ 80,000

Site SCADA System: A pharmaceutical company implemented a SCADA (Supervisory Control and Data Acquisition) and several bar code scanners for their Custom Packaging area. In addition, the SCADA system interfaced with the proprietary PPS (production planning system). The project included documentation, development, testing and validation per cGMP and GAMP (Good Automated Manufacturing Practice).

The primary user requirements of this project include the following: provide a secure interface to monitor equipment status, alarms, events, downtime, etc. from a single location including historical trending/analysis of operator actions, system alarms, etc.; provide complete, intuitive, consistent and readily-accessible documentation, procedures, forms and templates needed for compliance.; provide a secure interface to control process equipment.; allow the analysis of data to generate trends and reports without the need for customization.; Maintain data in an open format to allow for export (example MS Excel) for offline analysis, transfer to other systems, etc.; Establish a modular system for future expansions and deployments.; comply with computer validation and 21 CFR Part 11 issues requirements.; provide KPI (Key Performance Indicator) data in a consistent manner to allow for performance analysis amongst different process areas and production facility locations.; replace handwritten reports with electronic data entry and reporting (21 CFR Part 11 compliant).; Provide storage of data and printing of reports.; provide testing and documentation (including as-builts).; and consolidate best practice by combining customer's documents from various departments with MAVERICK Technologies' templates from past projects.

The business case for this project was based on the following: prevention of potential failures and hazards.; reduction of rework through immediate, automatic response to process disruptions.; reduction of waste and/or increase in yield through supervisor adjustments of the process to new setpoints determined by historical analysis.; identification of process bottlenecks in an effort to justify equipment maintenance, modifications and/or replacement.; and reduction of manpower requirements for supervision and operation of the system.

MAVERICK's scope included site survey, functional specification, system architecture development, PLC/HMI configuration, SAT, operator training and IOQ development/execution. The installation included a new system consisting of ControlLogix, iFix and iHistorian tied into the existing equipment PLCs.

MAVERICK Technologies and the client worked closely together in the client offices and MAVERICK's office during the course of the project.

Project #10

Project Value \$ 170,000

Site SCADA System: A pharmaceutical company implemented a SCADA (Supervisory Control and Data Acquisition) for their Facility Monitoring for alarm history and notification (via pagers). The project included instrumentation/electrical design, documentation, development, testing, installation and validation per cGMP and GAMP (Good Automated Manufacturing Practice).

The primary user requirements of this project include the following: provide a secure interface to monitor equipment status, alarms, events, downtime, etc. from a single location including historical trending/analysis of operator actions, system alarms, etc.; provide complete, intuitive, consistent and readily-accessible documentation, procedures, forms and templates needed for compliance.; provide a secure interface to control process equipment.; allow the analysis of data to generate trends and reports without the need for customization.; Maintain data in an open format to allow for export (example MS Excel) for offline analysis, transfer to other systems, etc.; Establish a modular system for future expansions and deployments.; comply with computer validation and 21 CFR Part 11 issues requirements.; provide KPI (Key Performance Indicator) data in a consistent manner to allow for performance analysis amongst different process areas and production facility locations.; replace handwritten reports with electronic data entry and reporting (21 CFR Part 11 compliant).; Provide storage of data and printing of reports.; provide testing and documentation (including as-builts).; and consolidate best practice by combining customer's documents from various departments with MAVERICK Technologies' templates from past projects.

The business case for this project was based on the following: prevention of potential failures and hazards.; reduction of rework through immediate, automatic response to process disruptions.; reduction of waste and/or increase in yield through supervisor adjustments of the process to new setpoints determined by historical analysis.; identification of process bottlenecks in an effort to justify equipment maintenance, modifications and/or replacement.; and reduction of manpower requirements for supervision and operation of the system.

MAVERICK's scope included site survey, functional specification, system architecture development, PLC/HMI configuration, SAT, operator training and IOQ development/execution. The installation included a new system consisting of ControlLogix, InTouch, InSQL and Suite Voyager tied into both the new and existing equipment PLCs.

MAVERICK Technologies and the client worked closely together in the client offices and MAVERICK's office during the course of the project. The overall project timeline was compressed by following MAVERICK's Project Execution Methodology.

Project #11

Project Value \$ 40,000

Site SCADA System: A pharmaceutical company implemented a SCADA (Supervisory Control and Data Acquisition) for their Facility Monitoring (CLEMS) for alarm history and notification (via pagers). The project included instrumentation/electrical design, documentation, development, testing, installation and validation per cGMP and GAMP (Good Automated Manufacturing Practice).

The primary user requirements of this project include the following: provide a secure interface to monitor equipment status, alarms, events, downtime, etc. from a single location including historical trending/analysis of operator actions, system alarms, etc.; provide complete, intuitive, consistent and readily-accessible documentation, procedures, forms and templates needed for compliance.; provide a secure interface to control process equipment.; allow the analysis of data to generate trends and reports without the need for customization.; maintain data in an open format to allow for export (example MS Excel) for offline analysis, transfer to other systems, etc.; establish a modular system for future expansions and deployments.; comply

with computer validation and 21 CFR Part 11 issues requirements.; provide storage of data and printing of reports.; Provide testing and documentation (including as-builts).; consolidate best practice by combining customer's documents from various departments with MAVERICK Technologies' templates from past projects.

The business case for this project was based on the following: prevention of potential failures and hazards.; reduction of rework through immediate, automatic response to process disruptions.; reduction of waste and/or increase in yield through supervisor adjustments of the process to new setpoints determined by historical analysis.; identification of process bottlenecks in an effort to justify equipment maintenance, modifications and/or replacement.; reduction of manpower requirements for supervision and operation of the system.; reduction of maintenance costs through replacement of equipment near the end of the useful life cycle.

MAVERICK's scope included site survey, functional specification, system architecture development, PLC/HMI configuration and SAT. The installation included additions to the existing system consisting of Allen Bradley PLCs and iFix.

MAVERICK Technologies and the client worked closely together in the client offices and MAVERICK's office during the course of the project. The overall project timeline was compressed by following MAVERICK's Project Execution Methodology.

Project #12

Project Value \$ 215,000

Site SCADA System Phase II: A pharmaceutical company implemented a SCADA (Supervisory Control and Data Acquisition) for their Facility Monitoring for alarm history and notification (via pagers). The project included instrumentation/electrical design, documentation, development, testing, installation and validation per cGMP and GAMP (Good Automated Manufacturing Practice).

The primary user requirements of this project include the following: provide a secure interface to monitor equipment status, alarms, events, downtime, etc. from a single location including historical trending/analysis of operator actions, system alarms, etc.; provide complete, intuitive, consistent and readily-accessible documentation, procedures, forms and templates needed for compliance.; provide a secure interface to control process equipment.; allow the analysis of data to generate trends and reports without the need for customization.; Maintain data in an open format to allow for export (example MS Excel) for offline analysis, transfer to other systems, etc.; Establish a modular system for future expansions and deployments.; comply with computer validation and 21 CFR Part 11 issues requirements.; provide KPI (Key Performance Indicator) data in a consistent manner to allow for performance analysis amongst different process areas and production facility locations.; replace handwritten reports with electronic data entry and reporting (21 CFR Part 11 compliant).; Provide storage of data and printing of reports.; provide testing and documentation (including as-builts).; and consolidate best practice by combining customer's documents from various departments with MAVERICK Technologies' templates from past projects.

The business case for this project was based on the following: prevention of potential failures and hazards.; reduction of rework through immediate, automatic response to process disruptions.; reduction of waste and/or increase in yield through supervisor adjustments of the process to new setpoints determined by historical analysis.; identification of process bottlenecks in an effort to justify equipment maintenance, modifications and/or replacement.; and reduction of manpower requirements for supervision and operation of the system.

MAVERICK's scope included site survey, functional specification, system architecture development, PLC/HMI configuration, SAT, operator training and IOQ development/execution. The installation included a new system consisting of ControlLogix, Archestra (Industrial Application Server), InSQL and Suite Voyager tied into both the new and existing equipment PLCs.

MAVERICK Technologies and the client worked closely together in the client offices and MAVERICK's office during the course of the project. The overall project timeline was compressed by following MAVERICK's Project Execution Methodology.

Project #13

Project Value \$ 150,000

Customer Site Support – DCS Support: MAVERICK has provided on-site technical support for a pharmaceutical company for several months providing a variety of services. The project included documentation, development, testing and validation per cGMP and GAMP (Good Automated Manufacturing Practice)

MAVERICK's scope included support of the Siemens Moore APS and APACS DCS.

MAVERICK Technologies and the client worked closely together in the client offices during the course of the project.

Project #14

Project Value \$ 105,000

Batch System 21 CFR Part 11 Remediation: A major pharmaceutical company completed the gap analysis and remediation plan for their site-wide automated batching system. At that point, MAVERICK was contracted to complete the Wonderware InTouch, InBatch and InSQL applications to ArcestrA (Industrial Application Server), and subsequent revalidation of the systems. The project included documentation, development, testing and validation per cGMP and GAMP (Good Automated Manufacturing Practice).

MAVERICK's scope included site survey, user requirements, functional specification (including risk assessment), system architecture development, PLC/HMI/Batch modifications, SOP updates and SAT/IOQ development/execution. The installation included ArcestrA (Industrial Application Server) and Allen Bradley PLCs.

MAVERICK Technologies and the client worked closely together during the course of the project. The overall project timeline was compressed by following MAVERICK's Project Execution Methodology.

MAVERICK Technologies, LLC.
265 Admiral Trost Road | Columbia, IL 62236
888.917.9109 | 618.281.9191 fax
info@mavtechglobal.com | www.mavtechglobal.com



engineering | systems integration | consulting