

> COMPUTER SYSTEM VALIDATION (CSV)

Maetrics engineers have degrees in Information Technology, or related fields, as well as experience in FDA regulated industries; specifically, the pharmaceutical, medical device and biotechnology industries. These engineers have been responsible for validation of computer systems and software according to FDA requirements, ensuring compliance with 21 CFR Part 11 regulations. Computer systems and software include ERP systems such as SAP, Laboratory Information Management Systems (LIMS), industry application software, manufacturing software controls, networks and computer hardware.

Maetrics recommends the application of the ISPE GAMP 5 guideline for most automated system validations.

> EXAMPLE CASE STUDY #1

Initial State

A global pharmaceutical manufacturer was upgrading its SAP system.

Objective

The primary objective was to provide QA testing and validation of the SAP upgrade including Supply Chain, Financials, Manufacturing, Warehousing, Orders to Cash and Resource Planning modules.

Maetrics Engagement

The following items and tasks led to a successful system upgrade:

- During the initial phase of the project, the biggest challenge was to develop compliant procedures and guidelines that utilized the existing validation structure and documentation due to the fact that this was an upgrade versus a new system.
- The project followed the GAMP 4.0 lifecycle approach to meet the compliance and quality requirements.
- Maetrics was responsible for drafting/reviewing the validation deliverables for the entire project.
- The documents included in this effort were the Validation Plan, Risk Assessment Plan, High Level Architecture, User Requirements Specification, Software Design Document, the SAP ECC 6.0 Installation Qualification (Test Environment), the SAP Production Environment IQ, System Test Plan/ System Test Strategy Documents, Guidelines for Test Scripts Review (Pre-execution and post execution) and Defects Review Guidelines.
- Assisted in drafting, and later reviewing, the Traceability Matrix.

- Maetrics identified gaps for testing and validation activities and reviewed the Validation Summary Report.
- Utilized the Mercury Quality Center as the testing tool, and all review and approvals of the test scripts were input into the MQC by the team.
- Maetrics assisted in the execution of the Test Environment IQ, and coordinated with the testing team.
- Provided guidance/direction to the script designing functional teams for Supply Chain Operations and Order to Cash projects, and helped draft the Guidelines for Test Scripts development.
- Participated in the enormous task of change controls for the broken objects for SAP Application and the ABAP programs and interfaces.
- Drafted/assisted with developing presentations and reports for the project meetings and metrics monitoring.

Results

All upgrade modules (Version 4.6 to ECC 6.0), including the Add-ons, Bolt-ons and the interfaces for SAP ECC 6.0 were tested and validated successfully.

> EXAMPLE CASE STUDY #2

Initial State

A biomedical company was building a startup facility.

Objective

The primary objective was to provide Computer System Validations (Controls) and guidance based upon regulatory requirements, guidance documents and industry standards for startup facilities and existing systems.

Maetrics Engagement

The following items and tasks led to successfully validated systems:

- Prepared CSV protocols for Biomedical Equipment in accordance with GAMP-4 and 21 CFR Part 11 utilizing URS, FRS, P& ID, Process Map, RS Batch, RS Logix 5000, and S-88 batch standards.
- Authored the Computer System Validation (Controls), IQ, OQ, and PQ for Liquid Filling Machines, Batch Processing Tanks, and Autoclaves.

- Authored Equipment IQ/OQs for various types of packaging equipment. This equipment included bottle labelers, vision systems and horizontal/vertical cartoners.
- Supervised validation contractors during the execution of assigned protocols to ensure validation deliverables were met. GDPs were utilized and protocol deviations were resolved.
- Coordinated the activities of validation resources to meet project milestones. Developed Validation Execution Plans to reduce the protocol execution time and resources.
- Prepared traceability matrices to ensure all parameters related to the process were identified and verified.
- Applied validation and engineering principles to the design and implementation of systems and process modifications while ensuring client safety expectations were maintained.

Results

Through completion of assigned activities and the supervision of additional resources, computer systems for the startup facilities and existing systems were successfully validated. The new facilities were fully functional at the conclusion of the engagement.