

The Situation

US based manufacturer of large sterile parenteral drug products sought assistance from Protocol Link with computer network and software validation consulting services.

The Solution

Protocol Link provided Subject Matter Experts (SMEs) to accomplish project goals in connection with computer and software validation. Tracking of project status was provided through detailed status reports, Gantt charts, and meetings with Client senior management during project execution. The entire project spanned a time period over than 2 years.

SAP R/3 Validation and Implementation: Managed project and Client personnel during validation of the SAP R/3 system, generated Standard Operating Procedures (SOPs), validation documentation (protocols, final reports) and change controls, and established entrance criteria for each phase of SAP R/3 Implementation.

- Validation / SOP Development Project Management: Reviewed and approved functional and technical specifications, investigative study test scripts, data migration test scripts, security test scripts, integration test scripts, procedures, and protocols. Provided employee and consultant training.
- Field Execution: Developed and field-executed protocols, facilitated training sessions, and addressed discrepancies arising during Investigative Studies, Data Migration and Integration Testing.
- Change Control Administration: Developed the SAP R/3 System Change Control SOP, facilitated training sessions for IT personnel, and completed > 750 change controls and system interfaces.

Data Center Relocation and Validation: Completed an assessment, inventory, and validation status of the components and equipment for the IT Network System / Data Center, and determined the requirements for its relocation within the Client facility (Phase 1). Generated and assisted with execution of the validation protocol for relocation of the Data Center, as well as writing of the validation final report (Phase 2).

- Initiated and completed change control(s) associated with the relocation efforts. Provided direction and guidance to Client IT personnel. Summarized findings of the assessment in a final report.
- Developed a schedule of activities required for validation of the relocated Data Center. Prepared and executed IQ/OQ protocols for verification of the server, switch and router, desktop, drawings, wires and cables, User Requirement Specifications (URS), security, backup system / restoration, environmental conditions, and associated new policies and procedures.

Magic Help Desk Software Validation: Assisted Client with software validation of the Magic Help Desk.

- Developed acceptance criteria, accounted for software upgrades and/or patch installations, prepared and field executed the IOQ protocol, and generated a final report on completion of the validation.
- Completed additional validation activities based on the addition of two (2) servers on the application side, replacement of the Oracle database with an SQL database, and upgrading of the Magic Help Desk application software version. Developed additional URS, prepared and field-executed validation IQ, OQ, and PQ protocols, and completed final reports.

Sarbanes-Oxley Policies and Procedures: Developed IT General Control policies and procedures consistent with Sarbanes-Oxley guidelines. Provided recommendations for requirements to Client IT management.

- Drafted IT General Control narratives, matrices and test scripts for identification and evaluation of corporate risks, specified the controls required for execution of the policies and procedures, determined and integrated the applicable requirements of Sarbanes-Oxley and their provisions into the narratives, and developed the test plans to challenge the specified controls.

The Result

Protocol Link successfully completed 100% of the planned effort associated with the entire project scope.