

The Situation

US based global Fortune 500 healthcare company sought assistance with validation and compliance consulting services for test method, process and database validation consulting services for its diagnostics division. Client also requested Protocol Link's assistance for validation and compliance consulting services in support of a consent decree signed with the U.S. Food and Drug Administration (FDA).

The Solution

Protocol Link provided Subject Matter Experts (SMEs) to assist Client with execution of the on-site project scope. Protocol Link SMEs conducted on-site reviews of the manufacturing processes, support systems, and control documentation, and provided observations / recommendations for remediation to Client management. The entire project spanned a time period of more than 5 years.

Test Method Characterization / Validation: Characterized and validated test methods for blood screening / immunodiagnostic assays to support US assay launch for use on Client's automated instruments / platforms.

- Prepared and received approvals for Test Method Characterization final reports. Summarized the characterization study data in final reports and determined the acceptance criteria for subsequent validation.
- Prepared and received approval for Test Method Validation protocols. Prepared and received approvals for final reports summarizing the results of the field execution of the validation protocols. Participated in cross functional team meetings and provided recommendations for addressing discrepancies that arose during execution of the protocols, as applicable.

Process Characterization / Validation: Characterized and validated processes for blood screening / immunodiagnostic assays to support US assay launch for use on Client's automated instruments / platforms.

- Prepared Process Characterization protocols for development / characterization of the various processes of a new blood screening assay. Prepared and received approval for the final reports summarizing the results of the field execution of the various process characterization protocols. Participated in cross functional team meetings and provided recommendations for addressing discrepancies that arose during execution of the protocols, as applicable. Determined the acceptance criteria for subsequent validation of these processes based on the process characterization data.
- Prepared Process Validation Approval protocols and final reports summarizing the results of protocol execution. Participated in cross functional team meetings and provided recommendations for addressing discrepancies that arose during execution of the protocols, as applicable.

FDA Consent Decree Support: Performed audit reviews of selected Client documentation for compliance. Managed and assisted in planning, scheduling, and resource allocation for development and implementation of filter qualification and test method / test method validation databases in response to the FDA Consent Decree.

- Conducted audit reviews of > 100 Process and Test Method Validation protocols and final reports. Dispositioned the Process and Test Method Validation packages and provided recommendations for remediation, as applicable, to Client management.
- Provided recommendations and support for protocol development for new validations.
- Created a database to compare the qualification of equipment used within manufacturing and testing documents associated with various assays of Client's blood analyzing platforms / instruments.

The Result

Utilizing the expertise and guidance provided by Protocol Link SMEs, numerous test methods and processes were successfully characterized and validated in preparation of assay launch in the U.S. In addition, based on Protocol Link SMEs' recommendations, certain Process and Test Method Validation packages were remediated to be compliant with FDA requirements.