

The Situation

US based leading solid dosage manufacturer sought assistance from Protocol Link to provide management and consulting support in the areas of responses to FDA-483 observations, quality systems, compliance assessments, operations, batch certification and release, cGMP documentation, and personnel training.

The Solution

Protocol Link assisted the Client in clearing backlogs of open customer complaint investigations and Annual Product Reviews (APRs), prepared and closed out exception investigations, ensured completion of corrective actions on completed exception investigations, revised and implemented Standard Operating Procedures (SOPs), and provided interim Operations Management assistance.

Protocol Link Subject Matter Experts (SMEs) also managed and coordinated operational activities, identified process / compliance improvement opportunities and assisted in their implementation, and completed FDA remediation plan follow-up activities, including responding to FDA-483 observations.

Tracking of project status was provided through status reports, project memoranda, and conference calls with Client senior management during project execution. The entire project spanned a time period of over 1 year.

QSCAP Initiatives / FDA Observation Responses: Completed response commitments to 23 FDA-483 observations related to product recall activities, API vendor audits, compliance assessments of field complaints, and APR process assessments. Assisted in evaluation, enhancement and scheduling of changes to compliance areas such as DEA controlled substance activities, Alert Limit Calculations reporting, audits, complaints management, APR reporting, recall activity procedures, and warehouse returned goods.

Quality Systems: Closed out outstanding and completed preparation of pending APRs, reduced the customer complaint backlog and addressed additional customer complaints, closed out outstanding and completed compliance reviews and approvals of additional variance investigations.

Production Systems: Validated bulk product hold times, prepared cGMP documentation (SOPs, Validation Master Plan, Out of Specification reports), completed process engineering and validation studies, provided recommendations for / implemented process improvement initiatives, and conducted personnel training.

Facilities, Utilities and Equipment: Prepared and field executed cleaning and passivation validation as well as equipment qualification protocols, completed investigations into and identified root causes for various equipment failure issues, and provided recommendations for corrective actions for these equipment failures.

Laboratory Control System: Prepared and field-executed various laboratory instrument qualification protocols, prepared final reports to summarize protocol execution results, developed an inventory database for laboratory cGMP documentation, completed assessments and ranking of the top 50 Client products,

The Result

Protocol Link successfully completed 100% of the planned effort associated with the entire project scope. In addition, the Protocol Link SME working in the capacity of Acting Interim Packaging Manager was instrumental in streamlining the batch record review and batch release processes. Furthermore, based upon direction provided by Protocol Link SMEs, responses to address 23 FDA-483 observations were formulated, approved by Client Senior Management, and forwarded to the FDA.