

The Situation

US-based leading pharmacy services provider of sterile IV and epidural preparations for pain management sought assistance from Protocol Link in the area of process improvement, compliance, and technical services.

The Solution

Protocol Link provided Subject Matter Experts (SMEs) for process improvement, compliance and validation initiatives. Assignments required hands-on services at multiple Client sites in the US with close team integration with Client resources. The project spanned a time period of more than 2 years.

Process Improvement Initiatives: Performed process reviews of Client's processing centers in order to identify prioritized opportunities (highly beneficial, potentially desirable, quick hitting) to reduce actual cost of operations while improving the quality of service.

- Completed quality and operational reviews of the processing center on-site operations, support functions, procedures, budget and actual performance data, controls, and product cost information.
- Prepared detailed process maps for Client site operations and a list of recommendations / process improvement initiatives via cost-benefit matrix evaluations to optimize and enhance the process flow and improve the overall cost per unit.

Syringe Compatibility and Validation Studies: Reviewed and provided recommendations to Client Senior Management regarding integration of syringe manufacturing equipment into Client's clean room operations.

- Determined the facility, utility and operational design requirements that would support the installation and performance of the selected syringe manufacturing and steam sterilization equipment, including work area design, critical utility requirements, overall workflow configuration, and compliance impact.
- Identified candidate drug products for potential utilization of the steam sterilization process. Prepared development / validation protocols and final reports for the validation of the appropriate steam sterilization cycles for each proven drug candidate.

Stability Program Management: Managed day-to-day tasks associated with the Client's stability program.

- Acted as a liaison between the Client's marketing group and contract laboratories. Prepared protocols, technical reviews, and justification papers. Performed research of possible issues that could affect the stability program. Provided support to field personnel and pharmacists. Ordered supplies and coordinated shipping of products.
- Performed operations-related tasks, including review and revision of Standard Operating Procedures (SOPs), provided quality approvals for control documentation, prepared supplemental technical evaluations, and completed product evaluations.

Exception Investigations: Performed exception investigations, ensuring that the subject data had been appropriately examined and confirmed that the relevant records were referenced or attached, as applicable.

- Prepared exception investigation reports for accuracy, adequacy and completeness and identified corrective actions to prevent recurrence. Ensured that effective CAPA actions were identified and implemented. Verified that the true root cause for each non-conformance was determined, using appropriate methodology, where feasible.

The Result

Utilizing the expertise and guidance provided by Protocol Link, Client process operations were improved and greatly enhanced, and a new strategy for the Client's parenteral drug product operations was created and implemented.