

The Situation

US based global manufacturer of injectable pharmaceutical products with manufacturing and packaging facilities located in Europe sought assistance from Protocol Link to prepare and submit Abbreviated New Drug Applications (ANDAs) for its drug products to the U.S. Food and Drug Administration (FDA).

The Solution

Protocol Link provided management and Regulatory Affairs (RA) experts for preparation and submission of ANDAs for drug products manufactured at the Client's manufacturing facility in Europe and intended for sale in the US. Subject Matter Experts (SMEs) were deployed in Europe and the US as needed to most effectively deliver the scope of services. The project spanned a time period of more than 1 year. The key work elements for accomplishment of project tasks were as follows:

Regulatory Submissions: Completed preparation of ANDAs in the Common Technical Document (CTD) format for several drug products, and subsequently submitted them to the FDA.

- Generated ANDA sections organized in the required format of five (5) modules - Module 1: Administrative and prescribing information (region specific), Module 2: Summaries and Overview, Module 3: Information on Product Quality, Module 4: Nonclinical Study Reports, and Module 5: Clinical Study Reports. Created Tables of Content (TOC) for each submission, converted submission documents from Microsoft Word into the pdf format, and provided bookmarks and hypertext links for all items listed in the TOC including tables, figures, publications, references, and associated appendices.
- Performed extensive quality checks and RA reviews to ensure that all required elements of the CTD were present within the ANDA sections, and were compliant with FDA requirements in terms of legibility, interpretability, adequacy, and compatibility of format and organization. Ensured that the narrative content of the ANDA sections and associated summaries and discussion were consistent and accurate, and did not contain contradictory information.
- Reviewed supporting documentation associated with each ANDA submission. Identified discrepancies and issues with the supporting documentation and forwarded them to the appropriate Client department(s) for revision via their change control process. Reviewed and responded to questions from various Client Department Managers in support of the ANDA submission. Provided recommendations for remediation of issues, as applicable. Conducted research relating to Adverse Drug Experience (ADE) reporting of the Reference Listed Drugs (RLD).

Labeling: Reviewed promotional materials (labels, inserts) of applicable drug products for compliance and completed preparation of promotional material review summaries. Provided review comments to Client senior management.

Document Review and Remediation: Completed reviews of control documentation (protocols, reports, standard operating procedures, batch records) and identified potential issues / discrepancies. Provided detailed recommendations for remediation of issues / discrepancies to Client senior management.

Contract Manufacturer cGMP Audits: Performed cGMP vendor qualification audits of third-party API manufacturers located in Europe and Asia. Conducted personnel interviews and facility assessments. Reviewed records for facility and equipment qualification and maintenance, validation documents, and other information with a focus on processes related to Client products. Prioritized observed discrepancies for client and provided recommendations for remediation of these discrepancies. Prepared and provided detailed audit reports summarizing audit performance and observations to Client Senior Management.

The Result

Utilizing the expertise and guidance provided by Protocol Link, several ANDAs were successfully submitted to FDA within Client-specified timelines.