

The Situation

US based pharmaceutical firm (client) engaged Protocol Link consulting for performing cGMP vendor qualification audits at its current and proposed, third-party API manufacturers (including a beta-lactam facility), analytical laboratory, and parenteral drug product manufacturers across Europe and Asia. Protocol Link provided scheduling, coordination, and performance of these audits.

The Solution

Protocol Link provided Senior Auditors for each audit, matching experience, location, and language skills as required. Audits were scheduled for efficient use of resources, combining multiple site visits into a single trip whenever possible. The audit scope included pre-audit preparation, on-site audits and post-audit follow-up.

Pre Audit

- Review of previous client audit findings and site/product-specific documentation
- Logistical coordination between client and auditors to ensure availability of key personnel
- Preparation of audit agenda and audit notification letters
- Development of customized audit checklists and materials for incorporating client requirements
- Staging and review of regulatory records relevant to the audit scope

On-site Audit

- Performance of on-site vendor qualification audits of 1-3 day duration, typically including interviews, facility tours, reviews of records for facility and equipment qualification and maintenance, validation documents, and other information, with a focus on the production of client products
- Verification of corrective action plan as submitted recently to the US FDA, where applicable
- Facilitating audit close-out meetings with site representatives

Post Audit

- Preparation of comprehensive audit reports summarizing audit performance and observations
- Coordination of audit follow-up and remediation tasks as required

The Result

A total of 10 contract manufacturers, with 12 sites were audited including API manufacturing, analytical laboratory services, and finished parenteral drug manufacturing. The audits were performed over a 16-month duration for drug substance as well as drug product manufacturing facilities located in Italy, Spain, Germany, Denmark, Norway, Ukraine, India and Japan.

Tracking of the project status was provided through frequent status reports, project reports, and conference calls with the client and its contract manufacturers.

Protocol Link successfully completed 100% of the planned audits on schedule and within budget.