

ADVANCED CLINICAL CASE STUDY

Inspection Readiness and Site Preparation

Business Challenge

A global pharmaceutical company acquired a unique product shortly after the FDA's acceptance of the NDA. Challenges included:

- FDA inspections of the sponsor and sites were imminent, leaving the company with little time to prepare
- The company was unfamiliar with both the product's development and clinical trials conducted
- Clinical trials had been completed several years prior by other pharmaceutical companies, study documents were archived, and sites had limited recall
- Several high-risk sites had closed business and dissolved since completing the study
- The company had limited staff and QA expertise to launch a full inspection preparation program under aggressive timelines

These factors left the company at risk in an inspection scenario, and put the success of the product's NDA in jeopardy.

Solution

The company engaged Advanced Clinical to provide comprehensive inspection preparation support. Activities included:

- Provided leadership and subject-matter expert guidance
- Advanced auditors and monitors were rapidly dispatched to investigator sites for inspection preparation activities including training and document review
- Organized paper TMF to industry standard (DIA Reference Model) and assessed the files for quality and completeness of content
- Comprehensive sponsor-monitor inspection training program provided to company staff onsite at their facility
- Hosted in-depth Investigator Site Inspection Training Webinar delivered to all sites that participated in the trials
- Provided industry renowned storyboards and incident summaries

Results

Advanced Clinical provided the structure for a comprehensive multifaceted rapidly engaged Inspection Preparation Program.

- Sponsor/Client and Sites were prepared for FDA Inspections
- FDA investigator site inspections were successful
- Storyboards and training materials were turned over to client for future use
- Company engaged Advanced Clinical to conduct inspection preparation activities including Risk-Impact Assessment, Gap Analyses, and Storyboarding for their next acquired compound

Quality Services

Infrastructure Support

- Quality planning
- Quality Support – Leadership/SME
- SOP Development

Specialized Consulting

- Inspection readiness
- Risk Management
- Root Cause investigations
- Storyboarding
- Training
- Data integrity

Audits

- TMF
- Documents
- Systems
- Sponsors
- Sites
- Vendors

Engagement Types

- Full outsourcing
- Project planning
- Consultants and staff