Case Study

ClinAudits, LLC

Phase 3 FDA & MHRA Pre-Inspection Readiness

Challenge

A small global pharmaceutical company had planned to use their internal QA staff to perform various types of GCP audits for a Phase 3 project in preparation for FDA and MHRA submissions. However, as deadlines approached and priorities shifted for staff, the company fell behind in its preparation process. Subsequently, they began searching for a nimble and reliable GCP auditing provider with global outreach to perform inspection readiness audits within a tight timeline. FDA/MHRA inspection readiness audits ensure that sites/vendors are aligned with applicable regulations, SOPs, working procedures, systems, processes, and identification of potential pitfalls.

Solution

Projects with aggressive timelines can be fraught with execution and quality risks. To limit those risks, ClinAudits provided this client a solution that leveraged ClinAudits extensive global network of auditors to complete 29 audits in 12 countries within 2.5 months. A project manager worked closely with client management providing flexibility and responsiveness as the scope and number of audits evolved during this engagement. Following the completion of each audit, ClinAudits peer reviewers ensured all deliverables met internal quality standards and ClinAudits provided ongoing metric reports.

Results

By leveraging proprietary SOPs and metric tools, ClinAudits was able to provide both effective and efficient auditing services, as well as robust metrics on audit trends. ClinAudits' global network of seasoned auditors, combined with the dedication of project managers and its streamlined auditing process, ensured the completion of this engagement within the required timeframe. ClinAudits continues to serve as a trusted partner for this client.

ClinAudits Advantages

- FDA/MHRA inspection readiness audits conducted by a third party are particularly beneficial to clients that lack the capacity to conduct an audit themselves or desire an unbiased audit.
- ClinAudits is an independent global auditing firm that examines a client's current GCP processes from a critical lens and prepares clients for future FDA/EMEA or other regulatory agency inspections. In this case, ClinAudits conducted 21 investigator site audits, 2 PV audits, 2 mock FDA/EMEA sponsor audits and 4 document audits for this client.
- ClinAudits' auditors have an average of 26 years of industry and 18 years of auditing experience. As a result, ClinAudits is a leader in the quality assurance field.
- Among surveyed clients, respondents indicated that ClinAudits' auditor experience was its most valuable resource.[1]
- ClinAudits' auditors are well versed in industry leading practices and are subject matter experts in their particular auditing fields.

"Rising capacity demands combined with a difficult global operating environment are pressuring sponsors to derive ever-higher levels of performance and efficiency in their outsourcing relationships. The growing prevalence of a functional service provider and alliance relationships holds the promise of delivering decreased operating expenses…and increased operating flexibility" [2]

Footnotes:

[1] Rutgers Consulting Team, 2014 Survey of ClinAudits Clients

[2] Vogel, J. and Getz, K. "Successful Outsourcing: Tracking Global CRO Usage". *Applied Clinical Trials.* 17 Aug 2009. Web.