How to Conduct a Regulatory Review to Ensure a Quality FDA Inspection

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BACKGROUND

In January 2023, the Early Drug Development (EDD) service was alerted to trial and regulatory management concerns from a study sponsor that could lead to an FDA inspection of two protocols. Given the operational constraints during the COVID-19 pandemic, the time during which most patients were enrolled in these trials, management staff began an in-depth review of all aspects of the trials. The comprehensive review conducted in preparation for this inspection is a process that can be utilized to maintain quality and for future potential audits.

CONCERN	GOAL
AE Reporting	Conduct a systemic assessment of reportable safety events with clinical staff collaboration.
Consenting Procedures	Review all patients with a focus on consent processes and eligibility verification.
Regulatory	Organize an internal Quality Assurance (QA) review of the regulatory binders.
Quality	Re-examine all monitoring letters and reconcile all pending findings.

METHODS

- Recruited additional staff, including internal QA auditors, to support preparation efforts.
- Listed all known safety events.
  Tracked initial and follow-up reports and their timelines.
  Submitted deviations for non-compliant AE reporting.
- Conducted systemic patient reviews including eligibility, consent processes and other supporting source documentation.
- Completed a regulatory review of DOAs, FDAs, 1572s
  Reviewed amendment submissions, protocol trainings, and sponsor safety reports.
- Created Notes to File to address corrections and discrepancies discovered during regulatory review.
- Conducted a review of all monitoring visit follow-up letters to ensure they were all filed.
  Reviewed the filed follow-up letters to ensure all findings were addressed and deviations filed accordingly.

RESULTS

Extensive preparation in the weeks leading up to the inspection guaranteed the team was as prepared as possible. All pending monitoring findings were reconciled, thorough documentation of safety events and deviations was completed, and essential regulatory documents were confirmed to be current. Additionally, after reviewing patient charts, gaps in source documentation were eliminated. During the audit, the team answered questions raised by the inspector with certainty and in real-time, a feat made possible by comprehensive groundwork.

LESSONS LEARNED

- The need for comprehensive and standardized audit preparation procedures to ensure inspection readiness.
- The importance of collaboration amongst the study team to maintain the quality of the trial throughout its lifespan.
- Observations of deficiencies which led the team to re-evaluate current operational workflows.