

GCP AUDITING: TAKE A QUALITY SNAPSHOT OF YOUR CLINICAL STUDY

Auditing brings an independent, quality assurance perspective to the clinical research landscape.

Investigational sites, sponsors, and vendors benefit from high-level process assessments and improvements. Auditors leverage extensive training and experience to help ensure subject safety, data integrity, and protocol and regulatory compliance.

When to Audit during a Clinical Study and Why?



During Early Enrollment

Snapshot of potential process-level problems (consenting, event reporting) in time to course-correct



When Hiring New Vendors

Qualify and verify product/service offerings



Shortly Before or After a PMA/NDA Submission

Assess inspection readiness, adequacy of processes, documentation, data integrity, and that subject safety has been ensured



Anytime!

With concerns of noncompliance, elevated rates or absence of AEs, high-risk sites or studies

Invest in the quality of your clinical program by
incorporating GCP Auditing into your studies today!