CLINICAL EXCELLENCE CONSULTING

FDA Findings During Audit

Safety & Efficacy • Common Findings • Trial Deficiencies • Documentation • Future FDA Preparedness

Safety

Identifying safety issues protects patients from harmful effects during clinical trials.

Efficacy

Assessing efficacy ensures treatments provide intended benefits for targeted conditions.

Compliance

Meeting FDA guidelines ensuresregulatory compliance and avoids approval delays.

Transparency

Transparency in findings builds trust with patients, investigators, and regulators.

Common FDA Findings in Trials

INFORMED CONSENT	Failure to obtain comprehensive informed consent from all participants.
PROTOCOL	Significant deviations from the approved clinical trial protocol.
DATA INTEGRITY	Inconsistencies or inaccuracies in clinical trial data reporting.
MONITORING	Insufficient oversight and monitoring of the trial's progress.
SAE REPORTING	Delayed or inadequate reporting of serious adverse events.
COMPLIANCE	Non-compliance with FDA regulations, guidelines, and requirements.

Common Deficiencies in Clinical Trials

INFORMED CONSENT	Ensure all participants fully understand the trial's purpose and risks before enrollment.
PROTOCOL	Strictly follow approved protocols to ensure study integrity and data reliability.
DATA INTEGRITY	Implement qu
ELIGIBILITY	Confirm all enrolled participants meet predefined eligibility criteria.
TIMELY REPORTING	Report adverse events and findings immediately per regulatory standards.

Preparing for Future FDA Changes

- Regularly review FDA announcements to align practices with latest regulations.
- Provide ongoing staff training on FDA compliance to minimize errors and improve data quality.
- Establish robust communication channels with regulatory bodies for timely feedback.

Documentation & Record Keeping

- Maintain records for all participants; ensure entries are accurate and timely.
- Store participant data confidentially and securely; comply with all regulations.
- Ensure records are easily accessible for audits and regulatory inspections.
- Retain records for the period specified by regulatory authorities; train all staff.