CLINICAL EXCELLENCE CONSULTING

Quality Assurance & Quality Control (QA/QC) in Clinical Research

Data Integrity • Patient Safety • Compliance • Audits • Training • QC Implementation • Technology

Data Integrity

Ensures trial data is accurate, reliable, and traceable, preventing inconsistencies.

Patient Safety

Ensures clinical processes adhere to safety protocols and timely AE reporting.

Regulatory Compliance

Facilitates adherence to international regulations, minimizing inspection findings.

Quality Culture

Fosters a culture that emphasizes quality at every stage of the clinical trial.

Role of Quality Assurance in Trials

SOPs	Create comprehensive procedures for informed consent and adverse event reporting.
RBQM	Risk-based quality management — focus oversight on critical data and processes.
TRAINING	Implement role-based training programs tied to specific protocol versions.
AUDITS	Conduct planned independent quality assurance audits across all trial sites.

QC Operational Implementation

SOURCE DATA	Verify critical data — inclusion/exclusion criteria and dosing — against source.
REAL-TIME	Conduct daily and weekly QC checks to identify inconsistencies promptly.
INFORMED CONSENT	Ensure correct version is signed with proper dates and signatures each time.
QUERY MGMT	Resolve data queries in a timely manner with root-cause analysis documentation.

Training & Qualification Best Practices

ROLE-BASED	Tailored training programs for each team role within the clinical trial.
LOGS	Document all training sessions tied to specific protocol versions.
VENDORS	Ensure all vendors meet regulatory and operational qualification standards.
REFRESHERS	Offer ongoing updates and refresher training based on protocol changes.
GAP ANALYSIS	Conduct evaluations to identify and address training gaps before audits.

Conducting Effective Internal Audits

PLAN	Identify audit objectives and define the scope and criteria clearly
GATHER	Collect necessary documents and data for a comprehensive audit review.
EVALUATE	Analyze findings against predefined standards and applicable regulations.
REPORT	Document audit results and suggest corrective actions with clear timelines.

Best Practices for High-Performing Trials

- QA designs robust systems; QC monitors execution for compliance and accuracy.
- Data trends inform QA feedback loops — driving continuous process improvement.
- CAPA: track and resolve corrective actions; foster quality at every trial stage.

Inspection Readiness & Technology

- Maintain current SOPs, audit trails, and records; conduct mock inspections regularly.
- Automate data entry; remote monitoring and blockchain ensure real-time QC.