



KAI Research, Inc., An Altarum Company Quality Assurance

Altarum Institute integrates independent research and client-centered consulting to deliver comprehensive, systems-based solutions that improve health and health care. A nonprofit, Altarum serves clients in both the public and private sectors.

Quality Assurance Defines Quality at KAI

Quality Assurance (QA) is an independent department within KAI that promotes excellence by ensuring adherence to standard operating procedures (SOPs) and Food and Drug Administration (FDA) regulations. KAI QA specialists have both formal training and years of experience participating in multidisciplinary clinical studies. Our QA expertise encompasses Good Clinical Practices (GCP), training, systems validation, auditing, data security, and Health Insurance Portability and Accountability Act compliance. KAI clients benefit from staff experience in a range of disciplines, including regulatory process, clinical data management, software life cycle practices, adverse event reporting, and good documentation practices.

The KAI QA Department has *successfully led the company through multiple FDA and industry GCP audits*. KAI has also supported sponsors and clinical sites during their onsite FDA audits by providing regulatory expertise, documentation and reports. KAI takes the approach that when our client is audited, we are audited, so supporting them is our highest priority.

For the National Institutes of Health and pharmaceutical clients, KAI

- ▲ Provides staff and clinical investigators with GCP training;
- ▲ Performs audits of labs, clinics, and other vendors; and
- ▲ Carries out data management and security reviews to verify that FDA 21 CFR 11 and National Institute of Standards and Technologies Federal Information Security management Act (FISMA) guidelines are followed.

KAI has written SOPs for pharmaceutical and government clients for all areas of the clinical trial life cycle, including

- ▲ Protocol development,
- ▲ Clinical trial management,
- ▲ Data collection,
- ▲ Statistical analysis,
- ▲ Document processing, and
- ▲ Adverse event reporting.

We also perform gap analysis of a client's SOPs in preparation for FDA audits.

Preparing Clients for FDA Audits

KAI QA staff carries out "mock FDA" onsite audits of sponsors, sites, and CROs to identify areas that would benefit from improved processes or training. All relevant documentation is reviewed along with an evaluation of the physical and data security. A debriefing identifies issues that need resolution. KAI provides guidance on how to interact with an auditor and how to respond to an auditor's request for information and documentation by outlining responsibilities of the staff involved in the audit and providing support for the company's audit lead coordinator (usually the QA Director).

Responding to an FDA Audit

After an FDA audit the client may be faced with having to respond to minor or major findings. KAI can provide guidance for the initial response to the FDA and the subsequent **Corrective and Preventive Action (CAPA)** plan. KAI has assisted clients in CAPA development and implementation. This is followed by monitoring the status of required activities, maintenance of the agreed-upon time line, and verification that the activities were carried out correctly.

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Validation Services

Validation of systems and applications is essential in the pharmaceutical and health research industries. When data are not recorded accurately and stored securely, a company's investment in drug development and clinical testing can be put at risk. KAI has created a **robust system life cycle process** that can be applied to any system servicing the pharmaceutical industry. We provide guidance on validation requirements and processes. KAI can carry out the initial validation as well as validation of upgrades, existing systems, and legacy systems. KAI systems have been audited according to FISMA and have received an Authorization to Operate by an external auditor for the National Cancer Institute.

Disaster Recovery

Disaster recovery needs to be built into every part of the organization. While it usually focuses on information technology, it should also include such things as gaining access to hardcopy documents, communication with staff, retrieval of data backups, and preparation of offsite facilities. KAI can assist or develop a disaster recovery plan that incorporates an inclusive continuity of operations. This is done by reviewing business critical functions and developing alternative practices ranging from manual workarounds to the deployment of a hot site. KAI can assess the disaster recovery needs of a specific organization and work with them to create a program that will work and meet industry expectations by implementing

- ▲ A disaster recovery plan,
- ▲ A threat assessment worksheet,
- ▲ A prevention inspection checklist,
- ▲ An information technology recovery plan, and
- ▲ An annual disaster recovery drill.

Quality Assurance Drives Continuous Improvement

QA facilitates continuous improvement through internal audits, policy and procedure creation, and support of corrective and preventive actions from external audit findings.

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