QUALITY ASSOCIATES INCORPORATED

A KONICA MINOLTA COMPANY

Quality Assurance & Scientific Support

QUALITY ASSURANCE & SCIENTIFIC SUPPORT

Quality Associates, Inc. (QAI) was established in 1986 to provide regulatory consulting services to the pharmaceutical and agrochemical industries. From our inception, Quality Assurance (QA) programs have been the cornerstone of QAI providing services for both Good Laboratory Practice (GLP) and Good Clinical Practice (GCP).

QAI's staff of quality assurance professionals were practicing scientists in regulated industries before joining QAI. Therefore, they conduct QA functions under GLP and GCP with an understanding of the science in the studies reviewed. QAI can assign an individual or team to any project as needed.

QAI has established more than 50 GLP programs for new and established companies, and helps support the implementation and maintenance of these programs. QAI provides support for all aspects of a client's quality assurance needs, and conducts introductory and advanced GLP seminars for technical staff and QA professionals. QAI also provides technical support services for Standard Operating Procedure (SOP) preparation, study design and protocol development; fulfills study director and monitor activities; and performs data review and report preparation. In addition to the above services, QAI maintains a fully compliant GLP archive for storage of documents, specimens or e-data.

QAI's corporate office is conveniently located near three major airports and is less than one hour by car from downtown Washington, D.C. and Baltimore, MD. QAI maintains additional offices in throughout the United States.

QAI auditors possess strong scientific and regulatory experience, which allows them to evaluate and create quality programs which meet the challenges of today's regulatory environment facing our clients.

ESTABLISHMENT AND IMPROVEMENTS OF GLP PROGRAMS

- Develop and implement your GLP program
- Develop and/or customize the SOP quality system
- Conduct basic and customized GLP training
- Assist management and Quality Assurance Unit during implementation

ACT AS AN INDEPENDENT QUALITY ASSURANCE UNIT

- Conduct protocol audits, in-phase inspections, data and report audits
- Prepare study audit reports and management reports
- Maintain QA study files
- Host FDA or EPA GLP and GCP inspections
- Conduct GLP training of current and new study personnel
- Conduct qualification audits of contract research organizations (CROs) and vendors

SUPPORT OF EXISTING QUALITY ASSURANCE UNITS

- Conduct GLP or GCP qualification audits of CROs
- Conduct in-phase audits of laboratory and field studies
- Conduct raw data and report audits
- Provide GLP gap analysis and mock FDA or EPA GLP and GCP audits
- Assist client during FDA or EPA GLP and GCP inspections

STANDARD OPERATING PROCEDURES DEVELOPMENT

- Provide basic package for GLP programs
- Develop customized SOPs for specific procedures
- Prepare equipment SOPs
- Prepare customized documentation forms

SCIENTIFIC SUPPORT - GLP

- Conduct technical evaluation of protocols
- Perform data reviews
- Provide study report review or preparation
- Fulfill study monitor or study director responsibilities
- Identify and qualify contractors

TRAINING PROGRAMS

- Introduction to the GLP
- Advanced GLP
  - for managers
  - for study directors
  - for other scientists (industry and academic)
  - for technical personnel
- On-site and off-site training
- Introductory and advanced seminars for QA professionals
- Introduction to electronic records and electronic signatures

ELECTRONIC RECORDS AND ELECTRONIC SIGNATURES SUPPORT

- Evaluate existing systems
- Provide gap analysis to 21 CFR Part 11 and to predicate rule
- Audit validations of computerized systems

THIRD-PARTY GCP AUDITORS

- CRO and vendor qualification
- Laboratory audits
- IRB audit
- Trial master file audit
- Clinical site audits
- Source documents audit
- Investigators brochure (IB) audit
- Database audit
- Bioanalytical data and report audits
- Clinical report audits
- IND and IDE submission audits

GLP ARCHIVING

- Limited and controlled access facility
- Storage of documents and specimens
- 24-hour security and fire systems monitoring
- HFC-227ea (FM200) fire suppression system
- Smoke detection by:
  - Laser particle-size analyzer, and
  - Multiple-port sampling
- Temperature and humidity controlled and monitored
- Electronic imaging of data and reports as certified true copies

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