QUALITY ASSURANCE & SCIENTIFIC SUPPORT

QUALITY ASSURANCE CONSULTANCY

A DIVISION OF QUALITY ASSOCIATES, INC.
A KONICA MINOLTA COMPANY

Quality Assurance Consultancy, a division of Quality Associates, Inc., is a leading provider of GxP quality assurance, scientific support and archiving solutions. For more than 35 years, we have been advising companies in the pharmaceutical and agrochemical industries, as well as educational organizations, on how to reduce time and expense in meeting critical internal and regulatory requirements.

EXPERTISE. DILIGENCE. RESILIENCE.

These three attributes are the hallmarks of Quality Assurance Consultancy. With unparalleled talent and industry knowledge, we create greater value at every touch point of the quality assurance (QA) lifecycle.

- Our team of QA professionals have proven track records as practicing scientists in regulated industries and know how to conduct QA functions under the Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) GLP and GCP principles.
- Our auditors possess strong scientific and regulatory experience, which allows them to evaluate and create quality programs to meet the challenges of today's regulatory environment facing our clients.
- Our dedicated experts have established more than 50 GLP programs for new and established companies in the pharmaceutical, agrochemical industries and more—providing full support in program implementation and maintenance.

PROVEN SOLUTIONS THAT YIELD BETTER RESULTS

Quality Assurance Consultancy provides full coverage or customized support for all aspects of your company's QA needs, including several highlights below:

Auditing: We can meet any of your auditing needs from study protocol, in-phase, data and report audits, as well as Contract Research Organization (CRO) facility qualification audits.

Training: Our specialists conduct introductory, refresher, as well as advanced GLP seminars, for technical staff and QA professionals.

Technical Support: We provide technical support services for Standard Operating Procedure (SOP) preparation, data form preparation, protocol development, etc.

Staff Augmentation: We can fill an array of specialized positions, such as study monitor, sponsor representative, report writing and more.

CREATING GREATER VALUE

With our services and expertise, we can help you reduce the time and expense of meeting critical internal and regulatory requirements.

"We view Quality Assurance Consultancy as a trusted resource. Their scientists consistently come to the table with recommendations and solutions that bring greater value to our program and processes."

— Recognized CRO

CAPABILITIES THAT SUPPORT YOUR CRITICAL EFFORTS

Through our track record of delivering consistently reliable services, see our full complement of GxP compliant capabilities. We can:

ESTABLISH AND IMPROVE YOUR GLP/GCP PROGRAMS

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

SERVE AS YOUR INDEPENDENT QUALITY ASSURANCE UNIT

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

SUPPORT YOUR 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

DEVELOP YOUR STANDARD OPERATING PROCEDURES

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

PROVIDE GLP SCIENTIFIC SUPPORT

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

CONDUCT TRAINING PROGRAMS

- Introductory GLP training
- Advanced GLP training for:
  - Managers
  - Study directors
  - Other scientists (industry and academic)
  - Technical personnel
- On-site and off-site training
- Introductory and advanced seminars for QA professionals

SUPPORT YOUR ELECTRONIC RECORDS AND ELECTRONIC SIGNATURES ENVIRONMENT

- Evaluate existing systems
- Provide gap analysis to 21 CFR Part 11 and to predicate rule
- Audit validations of computerized systems
- Assist in Developing Software Validation and Test Plans

SERVE AS YOUR GCP THIRD-PARTY 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

PROVIDE GLP/GCP ARCHIVING

We deliver comprehensive, reliable services with our best-in-class, secure storage solutions that have been validated through regularly scheduled inspections by multiple government agencies.

- Storage of documents and specimens
- Refrigeration, and -20 ºC and -80 ºC storage
- Backup generator
- 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
- Scanning/imaging of data and reports as certified True Copies

FOR MORE INFORMATION

Learn more about Quality Assurance Consultancy and our solutions by visiting **www.QualityAssociatesQA.com** or by calling one of our specialists at **410.884.9100**. Our 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.

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