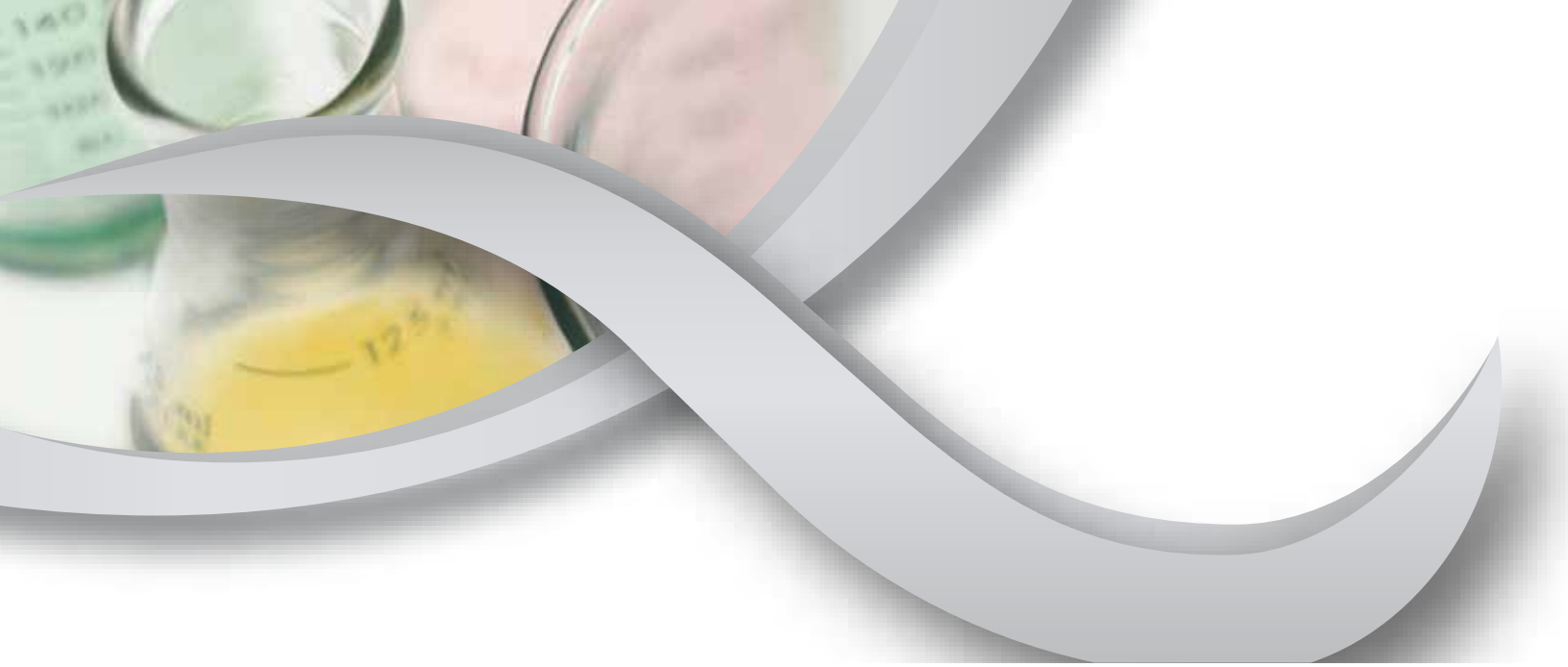
# quality assurance

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. Building from this initial foundation, QAI has developed scientific support and training programs that harmonize the interaction between study administration, technical, and quality assurance functions.

QUALITY ASSOCIATES INCORPORATED



# quality assurance

**QAI's** large staff of Quality Assurance professionals have practiced as scientists in regulated industries before joining QAI, including monitoring clinical studies and making regulatory submissions to FDA. Our auditors, therefore, conduct quality assurance functions under GLP and GCP with an understanding of the science and the regulations governing the studies reviewed. QAI can also assign a team to any project when needed.

**QAI** has established over 50 GLP programs for new and established companies, and helps support the implementation and maintenance of these GLP programs. QAI provides support for all aspects of a client's quality assurance unit, and conducts introductory and advanced GLP seminars for technical staff and QA professionals. QAI also provides technical support services for SOP preparation, study design and protocol development, fulfills the functions of study director or monitor, and performs data review and report preparation.

**QAI**'s corporate office is conveniently located near three major airports and is less than one hour by car from downtown Washington, DC and Baltimore, MD. QAI maintains additional offices in other locations within the U.S.

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

## Establishment and Improvements of GLP Programs

- Develop and implement a plan with management
- Develop and customize the SOP manual
- Conduct basic and customized GLP training of all study personnel
- Assist management and QAU during the implementation

## Act as the Independent Quality Assurance Unit

- Conduct protocol audits, in-phase inspections, data and report audits
- Prepare study audit reports and management reports
- Sign the QA statement in the final report
- Maintain a QA study file for each study
- Host FDA or EPA GLP and GCP inspections
- Maintain a copy of the master schedule
- Conduct GLP training of current and new study personnel
- Conduct qualification inspections of contract facilities

## Support of Existing Quality Assurance Units

- GLP or GCP qualification inspections of contract facilities
- In-phase inspections of laboratory and field studies
- Study raw data and report audits
- GLP gap analysis and mock FDA or EPA GLP and GCP inspections
- Assist client during FDA or EPA GLP and GCP inspections

## Standard Operating Procedures Development

- Basic package for GLP programs
- Customized SOP for specific technical procedures
- Generic equipment SOPs
- Customized documentation forms

## 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 programs
- Training in documentation procedures
- Introductory and advanced seminars for QA professionals
- Introduction to electronic records and electronic signatures
- Bioanalytical

## Scientific Support

- Design and write protocols
- Technical evaluation of protocols
- Data reviews
- Study report preparation
- Technical review of reports
- Fulfill study monitor or study director responsibilities
- Identify and qualify contractors

## Electronic Records and Electronic Signatures Support

- Evaluate existing systems
- Gap analysis to 21 CFR Part 11 and to predicate rules

## Third-Party GCP Auditors

- CRO and vendor qualification
- IRB audit
- Trial master file review
- Clinical site and CRO audits
- Source documents review
- Protocol review
- Investigators brochure (IB) audit
- Database audit
- Bioanalytical data and report audits
- Clinical reports audits
- IND and IDE submission audits
- NDA, BLA, and PMA submission audits

## GLP Archiving

- Limited and controlled access facility
- 24-hour security and fire systems monitoring
- HFC-227ea fire suppression system
- Smoke detection by:
  - laser particle-size analyzer, and
  - multiple-port sampling
- Temperature and humidity controlled and monitored
- Inventory maintained on database
- Electronic imaging of reports and data

## FDA Regulatory Services

- eCTD preparation
  - IND, IDE
  - NDA, BLA, PMA, ANDA
  - Annual report, DMF
- IDE, PMA, and 510(k) submission
- United States Agent services

scientific support
drug accountability audits
clinical site audits
electronic records
training programs

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