

MERRITT A. GRISSINGER, BS, RQAP-GLP

PQS, LLC – Quality Assurance Services

Phone: (540) 354-5008

Email: merritt@gas-mgrissinger.com

PROFESSIONAL SUMMARY

Fourteen years experience in various regulatory environments. Proficient in the application and interpretation of GLPs and veterinary GCPs in the preclinical and clinical stage development of drugs and in the nonclinical development and registration of pesticides.

EXPERIENCE

PQS, LLC – Quality Assurance Services, Bedford, Virginia (October 2006 – Present)

Pinnacle Quality Services is a multidisciplinary consulting firm, of which Quality Assurance Services (QAS) serves the pharmaceutical, pesticide, and animal health industries.

Co-founding Member

- Perform business administration duties including website content development, marketing, creation of internal Standard Operating Procedures, contract proposal and review
- Perform quality assurance inspections of study protocols, reports, raw data, and laboratory/field operations (clinical and non-clinical trials).
- Evaluate scientific data for compliance with U.S. and international guidelines and regulations (including GLPs).
- Perform thorough evaluations of client internal procedures (including regulatory compliance and study design, placement, monitoring, and reporting procedures); make recommendations for enhancing regulatory compliance and for streamlining the procedures to expedite submission and approval of product applications.
- Prepare and present training programs in regulatory compliance, the Good Clinical Practice guidelines for veterinary trials, and the Good Laboratory Practice regulations.
- Prepare Standard Operating Procedures for existing and or developing GLP facilities

Covance Laboratories, Vienna, Virginia (October 2005 - July 2006)

Covance is a leading contract toxicology, chemistry, and environmental research organization.

Performed contracted Senior Quality Assurance Auditor duties including, but not limited to inspection of lab-generated mammalian and genetic toxicology data and reports for compliance with appropriate Good Laboratory Practice regulations, company SOPs and sponsor-approved protocols.

SciReg, Inc., Woodbridge, VA (July 2002 – September 2005)

SciReg, Inc. is a multidisciplinary scientific, regulatory, and quality assurance consulting firm primarily serving the pharmaceutical, pesticide, and animal health industries.

Regulatory Specialist

- Responsible for keeping clients informed of relevant regulatory matters affecting their products.

EXPERIENCE (Cont.)

- Perform quality assurance inspections of study protocols, reports, raw data, and laboratory/field operations (clinical and non-clinical trials).
- Evaluate scientific data for compliance with U.S. and international guidelines and regulations (including GLPs).
- Solicit, obtain, and evaluate bids from contract laboratories and make recommendations to clients regarding contracting of studies.
- Perform thorough evaluations of client internal procedures (including regulatory compliance and study design, placement, monitoring, and reporting procedures); make recommendations for enhancing regulatory compliance and for streamlining the procedures to expedite submission and approval of product applications.
- Prepare and present training programs in regulatory compliance, the Good Clinical Practice guidelines for veterinary trials, and the Good Laboratory Practice regulations.
- Perform scientific monitoring functions for various studies required to support product approvals.
- Prepare regulatory submissions to EPA and FDA.
- Prepare and maintain state registrations for clients' pesticide products.
- Prepare Standard Operating Procedures for existing and or developing GLP facilities

Covance Laboratories, Vienna, Virginia (January 1999 - July 2002)

Supervisor, Quality Assurance, September 2000 – June 2002

- Functioned in same capacity as Group Leader (title changed to reflect Position Description).

Group Leader, Quality Assurance, January 1999 - September 2000

- Provided management of staff and auditing procedures for nonclinical laboratory studies, facilities, vendors and support areas to assure the integrity of studies and adherence to Good Laboratory Practices (GLPs), protocols and Standard Operating Procedures (SOPs).
- Performed financial analysis of group costs, evaluated work load, assisted in establishing department priorities, scheduled and assigned appropriate staff to participate in QAU activities.
- Consulted with clients with respect to methods, procedures, record keeping, etc.
- Represented the company in a quality assurance capacity during regulatory agency inspections, association meetings and client visits.
- Provided assistance to various departments, study directors/project managers, management personnel, etc. on QAU interpretations and recommendations.

SRA International, Inc., Washington, D.C. (March 1997 - January 1999)

SRA International is a scientific and regulatory consulting firm serving the pharmaceutical, pesticide, medical device, and chemical industries.

QA Liaison, June 1998 - January 1999

- Responsible for scheduling and performing site inspections for six veterinary clinical trial sites in addition to contract laboratories/feed mills.
- Authored and presented training programs emphasizing the FDA/CVM Guidance document Good Target Animal Study Practice Guidelines.
- Responsible for establishing archive/filing system for clinical trial.

EXPERIENCE (Cont.)

- Authored and implemented audit plan for auditing clinical trial utilizing multiple sites with site-specific protocols and SOPs.
- Managed activities of four auditors.
- Performed weekly data inspections for clinical sites.
- Audited or delegated reviews of other third-party QA protocols, statistical and/or final reports.

Regulatory Scientist, March 1997 - June 1998

- Interpreted and analyzed multi-disciplinary studies conducted to support EPA or FDA registrations/ approvals.
- Performed laboratory site inspections, protocol and GLP compliance monitoring.
- Audited data and reports for compliance with appropriate regulations and scientific merit.
- Solicited, obtained, and evaluated bids from contract laboratories and made recommendations to clients regarding contracting of studies.
- Interacted with clients and EPA personnel with regard to data requirements, regulations, project status, regulatory strategies and scientific matters.
- Compiled EPA and client status reports, new product registrations and reregistrations.

Covance Laboratories (June 1992 - March 1997)

Quality Assurance Auditor, April 1995 - March 1997

Quality Assurance Technician, October 1993 - April 1995

Study Technician II, Rodent Toxicology, June 1992 - October 1993

MEMBERSHIPS

Society of Quality Assurance, active member, 1995-present

National Capitol Area Regional Society of Quality Assurance, active member, 1994-present

- Serving as Vice President, President and Immediate Past President, 2002-2005
- Board of Directors, 1998-1999 and 2006-2007

PROFESSIONAL CERTIFICATIONS

Registered Quality Assurance Professional-GLPs since 1997

American Association for Laboratory Animal Science Assistant Technician

EDUCATION

B.S., Biology, 1992, Virginia Polytechnic Institute and State University, Blacksburg, Virginia