NOBLE LIFE SCIENCES

Your Preclinical Development Partner

Drug, Device, & Vaccine Development ♦ GLP & non-GLP Services ♦ Vivarium Services

POSITION SEARCH
QUALITY ASSURANCE (QA) OFFICER

The Company: Noble Life Sciences (Woodbine, MD) is a contract research organization (CRO) providing services in the fields of preclinical drug, vaccine and medical device development, from product discovery to GLP-compliant studies for regulatory submissions. The company offers integrated *in vitro* and *in vivo* services, including cellular and animal disease model development and experimental design, non-GLP and GLP efficacy, toxicity, biodistribution and product release studies in both small and large animals, and vivarium services. The company also offers custom polyclonal antibody production services, as well as research animal tissue and sourcing. NLS operates out of a 24,000 sq. ft. SPF animal housing and support space, with conditioned indoor housing for large animals, five acres of fenced outdoor housing for large animals, two fully equipped surgical suites, a necropsy suite and a sample processing lab. The facility includes ABSL-2+ and BSL-2 capabilities, an automated security system, automated equipment and HVAC monitoring systems and a 100% back-up generator. NLS is AAALACi accredited, USDA licensed, OLAW compliant, FDA inspected and successfully audited by numerous clients.

The Position: The QA Officer is a key position within the organization with significant prospects for career growth as the company continues to increase the breadth and scope of its business. This position reports directly to Facility Manager and/or Sr. Vice President, Consulting Quality Assurance Unit.

Responsibilities include but are not limited to:

1. Become and maintain intimate familiarity with all applicable FDA and EPA GLP and other appropriate regulations and guidelines as well as with the company SOPs and other QA systems.
2. Maintain a copy of the master schedule of GLP studies conducted at the testing facility.
3. Review protocols for compliance to GLP regulations and NLS's SOPs.
4. Maintain copies of protocols for all GLP studies.
5. Develop and maintain a schedule of phase inspections for each GLP study.
6. Inspect study phases for on-going studies for compliance with the protocol, SOPs, and GLP regulations at intervals adequate to assure integrity of each study.
7. Audit data from GLP studies for compliance with GLPs, protocol and NLS SOPs.
8. Perform audits to assure that all final reports accurately reflect the raw data and all methods and procedures specified in the protocol and SOPs.
9. Assure for GLP studies that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation.

10. Report findings noted during inspections/audits to management and study director and maintain written and properly signed records of the inspections/audits. Ensure that any findings which are likely to affect study integrity are immediately reported to the study director and management.

11. Prepare and sign a statement to be included with each final report specifying dates QA inspections were made and findings reported to study director and management.

12. Periodically report to management and study directors written status reports on each study, noting any problems and corrective actions taken.

13. Perform periodic facility inspections and reporting results to facility management and study directors if GLP studies are ongoing. Maintain written and signed records for these inspections.

14. Write QA SOPs, periodically reviewing laboratory SOPs for compliance with actual procedures being performed and recommending SOP revisions when necessary.

15. Perform inspections of GLP subcontract laboratories to ensure compliance of study phases with GLP requirements and participate in quality assessments of other critical vendors.

16. When specified in the protocol, serve as quality assurance lead for the study, including ensuring adequate QA coverage at any test sites and liaising with test site QA.

17. Organize and provide GLP training for NLS staff.

18. Reports to Facility Manager and/or Sr. Vice President, Consulting Quality Assurance Unit.

Qualifications and Specifications:

- A minimum of an undergraduate degree, with preference for a graduate degree, in a life science field relevant to the business of NLS.

- At least one years experience with increasing responsibility in a QA position and/or similar operational role in a GLP environment.

- Ability to operate in a smaller company environment that requires hands-on implementation, optimal use of limited resources and an ability to work closely with others in a small team setting.

- Successful track record of interaction with QA management personnel in biopharmaceutical and/or medical device companies.

- Self-starter – individual needs to be aggressive and persistent in achieving the company's operational and business objectives.

- Ability to establish and maintain SOPs and QA systems in an orderly manner.

- Demonstrated attention to detail.

- Excellent team player, strong communication skills within and outside the organization.

Noble Life Sciences is an equal opportunity employer and offers professional development opportunities and comprehensive benefits package.