NOBLE LIFE SCIENCES

Your Preclinical Development Partner

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

POSITION SEARCH
QUALITY CONTROL (QC) ASSOCIATE

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 QC Associate – 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 Sr. Vice President and a 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. Supervise day to day quality control operations and documentation
3. Assist in writing and reviewing standard operating procedures, study protocols and reports
4. Direct and coordinate employee training program, and maintain employee training files
5. Coordinate in-house and external routine maintenance including calibration and certification and maintenance of laboratory equipment
6. Review data generated from studies
7. Maintain the inventory of laboratory supplies and order supplies as needed
8. Write facility and SOP deviation reports
9. Maintain general housekeeping activities in the lab including checking and keeping track of the expiration dates for various reagents and supplies
10. Should identify and resolve gaps in day to day processes.

11. Assist in internal, client and regulatory audits as required

12. Perform other duties as assigned.

Qualifications and Specifications:

- A minimum of bachelors degree in scientific discipline
- At least one years experience with increasing responsibility in a QC 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 QC 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.