QUALITY CONTROL DOCUMENT SPECIALIST

This position will be responsible for activities involving quality assurance and compliance with applicable regulatory requirements within the Quality Control Group.

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following. Other duties may be assigned.

- Performs the compliance review and approval of all documentation related to disposition of clinical products and research testing documentation;
- Generation of associated deviations, investigations, and OOS reports;
- Generation of change controls;
- Performing routine internal audits of quality control processes;
- Scheduling, initiation, and review of stability study data
- Assisting in all other QC related activities as required:
- Follows Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs)
- Other duties as assigned or determined by Area Management

EDUCATION and/or EXPERIENCE

- Associate's Degree or equivalent; or one to three years related experience and/or training; or equivalent combination of education and experience.
- Experience with plasmid purification and microbiology techniques is preferred.
- Technical writing experience is a must. The technical writing aspect will utilize knowledge, experience and understanding of documentation best practices to produce high-quality technical documentation including deviation and investigation reports, SOP's, and other supporting documentation.
- Bioprocessing and GMP experience is a plus.

Equal Opportunity Employer