MANUFACTURING DOCUMENT SPECIALIST

This position will be responsible for activities involving compliance with applicable regulatory requirements within Manufacturing Group.

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following:

- Performs the compliance review and approval of all batch documentation related to disposition of clinical products
- Author deviations and investigations
- Writing/Reviewing Standard Operating Procedures for manufacturing department
- Review Master Production Records
- Performing routine internal audits of Manufacturing processes
- Write and review protocols for development reports, IQ/OQ's and validations
- 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