QUALITY ASSURANCE SPECIALIST

This position will primarily be responsible for quality assurance and compliance activities related to ensuring that production, testing, and associated documentation meets applicable regulatory and client requirements.

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

- Assembling of batch documentation related to disposition products;
- Processing CAPAs;
- Performing routine internal audits of manufacturing and quality control processes;
- Maintaining supplier files;
- Performing supplier audits;
- Maintaining audit files;
- Responsible for proper documentation of equipment;
- Conducting training for new employees
- Assist in development of quality system SOPs
- Maintain inventory of products
- Follow Good Manufacturing Practices (GMPs) and, Standard Operating Procedures (SOPs)
- Work with other departments to solve customer/product issues as necessary
- Review and approve Certificate of Analysis on finished products, as needed
- Print and approve product labels based on client / documented requirements
- Other QA duties as assigned or determined by Area Management

EDUCATION and/or EXPERIENCE

- Bachelor's degree from four-year college or university; or three to five years related experience and/or training; or equivalent combination of education and experience.
- Experience with plasmid purification and microbiology techniques is preferred. Bioprocessing and GMP experience is a plus.