QUALITY....IT'S IN OUR DNA™

Manufacturing Document Specialist

SUMMARY

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

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following.

- Performs the compliance review and approval of all manufacturing batch documentation related to disposition of clinical products
- Author/Review 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

REQUIREMENTS

- 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.
- Bioprocessing and GMP experience is a plus.

Contract to hire position

VGXI is an Equal Opportunity Employer.