QUALITY....IT'S IN OUR DNA™

Validation Specialist

Support process and product quality programs including process validation, equipment calibration programs, and process monitoring activities by writing verification/validation documents, executing qualification tests, compiling data, drafting summary reports, and reviewing validation documentation to ensure products are manufactured in accordance with applicable regulatory guidelines, manufacturer's specifications, client's specifications, and VGXI's requirements. Review, update and work with various departments to develop SOPs for existing and new equipment/ processes.

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

- Support the validation function by assisting with the development of validation documentation, executing qualification protocols, compiling data, and writing reports.
- Support new product scale-up, process optimization, technology transfer, and process validation activities.
- Participate on project teams responsible for the implementation of product enhancements.
- Maintain validation schedules/timelines.
- Maintain re-validation schedule and validation files.
- Mentor junior staff and support team growth though the supervision of assigned projects.
- Monitor publications, presentations, etc., to stay current on all processing technology and recommend process improvements.
- Report back to QA Manager on the general status of operations and specific issues of concern as needed.

QUALIFICATIONS

- Bachelor's Degree or equivalent; or one to three years related experience and/or training; or equivalent combination of education and experience.
- Experience with in a pharmaceutical/biologics environment is preferred
- GMP experience is a plus.

Contract to hire position.

VGXI is an Equal Opportunity Employer.