VALIDATION SPECIALIST

Support process and product quality programs including process, testing, and software validation, equipment calibration programs, and process monitoring activities by writing simple 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 / tests / 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.
- Support QC validation of in-process and release assays
- Support qualification and re-qualification of QC test instrumentation
- Participate on project teams responsible for implementation of product enhancements.
- Maintaining validation schedules/timelines
- 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 over time.
- Report back to QA Manager on the general status of operations and specific issues of concern as needed.

EDUCATION and/or EXPERIENCE

Bachelor's Degree or equivalent; or one to three years related experience and/or training; or equivalent combination of education and experience.

Equal Opportunity Employer