



VALIDATION ENGINEER/SPECIALIST

The Validation Engineer/Specialist develops and executes protocols to ensure compliance with the Food and Drug Administration (FDA) and current Good Manufacturing Practice (cGMP) regulations. Most positions involve working in a project team environment. Some positions require regular travel to client sites that may be located outside our office locations.

Minimum Requirements:

- A Bachelors degree in Engineering, Management, Life Sciences, or other related technical field (or equivalent military training) **or** three or more years experience in pharmaceutical or other regulated industry or a combination of education and experience.
- Ability to work independently with minimal supervision.
- Ability to work in a project team environment and contribute effectively to the mission and success of the team.
- Excellent writing skills.
- Problem identification and solving ability.
- Proficiency with use of computers and standard software programs (e.g. Word and Excel).
- Strong communication and interpersonal skills ensuring the ability to interact with clients, other contractor personnel and peers in a professional manner.
- Climbing stairs, climbing on equipment such as tanks. Moderate lifting. Walking.
- An understanding of the drug development and manufacturing processes employed in the pharmaceutical industry.
- Ability to properly gown, enter an aseptic area, and perform activity in an aseptic area in compliance with customer requirements. (Include if applies)
- Ability to work safely and comply with company/customer safety procedures for safety-sensitive areas.

Responsibilities:

- Develop protocol, SOP, engineering test methods
- Test execution
- Final report development
- Interacting with project team and clients to complete project goals
- Work with technical drawings such as P&IDs, instrument loop drawings and isometrics.
- Apply “good documentation practices” consistent with the requirements of government regulated industries.
- Learn principles of operation of new equipment and associated controls; identify critical parameters affecting quality or safety; and relate those critical equipment parameters to the overall production process. This may require the individual to locate and obtain associated specifications, drawings, and technical documentation and walk down equipment in the plant
- Development of specialized skills or a diversity of processing knowledge and experience.

Protocol development requires the ability to evaluate equipment and systems, identify critical parameters/components, and develop appropriate test methods, sampling plans and data records. Test execution involves performing defined test requirements, identifying and resolving test discrepancies and accurately recording and summarizing test results. Test personnel may also support development of operations support programs, including standard operating procedures, maintenance program definition and training.