Senior Validation Consultant (Malvern, PA, Raritan, NJ, Spring House, PA)

Pinnaql Inc. is seeking an experienced candidate with strong eye for detail who can perform activities related to the qualification and life-cycle management of computerized lab instruments and mechanical equipment in an analytical laboratory in a pharmaceutical GMP facility. The role will require excellent interpersonal skills, and the ideal candidate must be able to develop strong team relationships.

This is a salaried role at Pinnaql with the requirement that any candidate can work for our client onsite and manage both Pinnaql and client expectations seamlessly.

Responsibilities:

- Support our client in preparing for the qualification; this includes the organization and co-ordination of kick-off and status follow up meetings with all involved parties.
- Prepare the qualification documents (Plans, Protocols, Reports, etc.) and execute test scripts according to established procedures.
- Execute and manage change controls.
- Ensure that testing performed during all qualification/validation activities is consistent with approved protocols, policies, guidelines and SOPs, resolving all qualification discrepancies when applicable.
- Write, investigate and review discrepancies and observations; perform root-cause analysis and identify corrective and preventive actions when required.
- Provide problem solving support to our clients.

Requirements

- BA / BS in a Science related major (Chemistry, Biology) or related field with 3-5 years relevant experience or equivalent combination of education and experience.
- Experience with the qualification of computerized lab systems.
- Hands-on experience with a variety of typical analytical lab instruments.
- Good understanding of the Code of Federal Regulations, GxPs, FDA regulations governing validated applications including (21 CFR Parts 11).
- Ability to effectively interact with a wide range of individuals at all levels of the organization.
- Excellent organization skills and the ability to balance multiple projects and priorities.
- Ability to work independently in a fast-paced, deadline-oriented organization.

What we offer

- Challenging long-term projects in qualification/validation and GMP compliance.
- Personalized internal training program.
- To be a part of a young, dynamic, growing organization.
- Competitive salary and benefits package including paid time off program, healthcare insurance, dental plan, long-term disability and life insurance.