NEXA
ENTERPRISE ASSET MANAGEMENT

Validation Engineer I

Who we are:

NEXA | EAM, founded in 2015 in Ireland, began with just one client and one employee. Today, we are a trusted advisor to leading companies in the Life Sciences industry around the world with a growing team of over 100 employees. Our team of understanding, talented professionals create value for leading Life Sciences companies by focusing on the delivery of Asset Management solutions to enable world-class production. Our commitment to achieving excellence helps our clients accelerate the delivery of life-changing products to market. We achieve this through our people, who are always our highest priority. Are you ready to join a growing team that values your contributions, development, and wellness?

Here's what you'll get:

- Work from home flexibility.
- Manage your own time on assigned projects.
- Never a dull moment! - Exposure to diverse projects with collaborative teams.
- Opportunity to explore new places and restaurants across the U.S.!
- Covered travel expenses- you even get your own credit card! (For approved incidental charges)
- A work environment that is both rewarding and challenging.
- Successful training program to acclimate you in your new role & continued learning, including tuition reimbursement and weekly dedicated time towards development.
- Competitive Full-Time Benefits including Paid Time Off, Health, Retirement, Education & **more**!
- In-person and virtual social gatherings and events.

NEXA |EAM is searching for:

A full-time, Validation Engineer I near Cherry Hill, NJ to support our clients with project needs. You will travel up to 75% of the time in the U.S. to contribute at different client sites. You will report to a NEXA Validation Manager.

About the job:

- Develop, prepare, and execute PM, IQ, OQ, and PQ protocols for our client's laboratory equipment in support of GMP/FDA requirements.
- Follow Good Laboratory/Documentation Practices when operating lab equipment and performing technical writing.
- Troubleshoot electrical, mechanical, and computerized software/ systems.
- Other duties as required.

We are looking for people with:

- Bachelor's degree in Chemistry, Engineering, Science, or Computer Science.
- In the absence of the above, 2-5 years of Validation experience, preferably in an FDA related manufacturing or laboratory operation.
- Ability to work independently, as well as partnering with members of the team to complete onsite projects.
- Strong interpersonal skills: ensuring the ability to interact with clients and peers in a professional manner.
- Strong troubleshooting and problem-solving skills.

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- Ability to work in a fast-paced environment while supporting multiple and changing priorities.
- Proficient with operating Windows computers, MS Office, and ability to quickly learn new software.
    - Advanced skills in MS Word / Excel are a plus.
- Ability to continually learn cross-functional services (Calibration, Validation, and Laboratory Instrument Services).
    - HPLCs.
    - GCs.
    - UV-VIS.
    - Autoclave sterilization studies.
    - Temperature and Humidity Warehouse mapping studies.
    - Controlled Temperature Unit studies (Ovens, incubators, stability chambers, refrigerators, freezers, etc.).
    - Glassware washer studies.
    - Analytical balance qualifications to USP-41 specifications.
    - Other areas of expertise within the scope of the Compliance Team's operations.
- A Driver's license.
- Ability to work in different temperature environments- including but not limited to heat and freezers of -40 degrees.
- Ability to lift, push, pull, and carry up to 75 pounds with another person.

Desirable:

- Familiarity with Kaye Validator and other relevant qualification equipment.
- Knowledge of FDA regulations, pharmaceutical GMPs (21 CFR 210 and 211), and/or ISO regulations.
- Familiar with pharmaceutical, biotech, or medical device manufacturing process, facilities and equipment, calibration, IQ, OQ, PQ, and development of SOPs.
- Experience with software and process control applications is desirable- GAMP 5 guidance familiarity a plus.
- Establish and maintain close communication with assigned clients to ensure superior customer satisfaction.
- Ability to plan and prioritize diversified workload independently with minimal supervision.
- Excellent verbal communication and technical writing skills with strong attention to detail.
- Familiarity with Kaye Validator and other relevant qualification equipment.

You will be a match if you are:

- Understanding of your client's and colleague's needs.
- Willing to operate the NEXA way, every day, by showing relentless drive in ensuring success.
- Attentive to detail and believe passionately in "Right First Time."
- Proactive in everything you do.
- An advocate of continuous improvement, which is vital to continued success.
- Adaptable and flexible to meet client and project needs.

If this sounds like you, apply today by: Emailing your updated resume to our People Experience Warrioress – Candalee Alicea at calicea@nexaeam.com

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Qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, sexual orientation, gender identity, disability or protected veteran status.

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