Validation Specialist - Thousand Oaks, CA

Description:

Gabe, Inc.® is searching for a Validation Specialist with experience in Commissioning, Qualification and Validation of system and hardware components associated with analytical instruments.

Responsibilities:

- Collaborate with client to develop C&Q strategies that are in compliance with local, corporate & regulatory regulations.
- Collaborate / Approve / Execute IQ, OQ & PQ protocols per approved timeframes.
- Develop/Approve documentation including, but not limited to: SOPs, Risk Assessments, Validation Plans, User Requirements, IQ/OQ/PQ Protocols, Requirements Traceability Matrices, and Summary Reports
- Responsible for test execution, exception reporting, assisting in exception analysis and resolution in a GMP compliant manner.
- Facilitate and generate Data Integrity assessments.
- Manage cross functional team meetings which will interpret the client's needs and drive decision to meet expectations.

Education:

- BS/BA in Engineering, Computer Science, Biological or other related discipline or equivalent work experience.

Experience:

- 2-5 years of experience with performing validation activities (preferred analytical equipment).
- Technical understanding of clinical laboratory operations (desired).
- Previous experience working in an FDA regulated and/or GMP environment.
- Working knowledge of Data Integrity principles (CFR Part 11).
- Strong analytical skills with ability to translate sometimes ambiguous data sets into actionable insights and recommendations.
- Excellent (written and verbal) communication and interpersonal skills, solid organizational skills, and ability to contribute to a collaborative, flexible work environment.
- Expert knowledge of cGMP documentation practices required
- Working knowledge in utilizing appropriate root-cause analysis tools & techniques
- Basic computer skills including experience in the use of Microsoft word, Excel, etc.

Benefits:

- Gabe, Inc.® offers a competitive compensation and benefits package.
- Position is located at the Amgen Campus in Thousand Oaks, CA.
- Normal working hours are 8:00 a.m. to 5:00 p.m. Monday through Friday, however irregular working hours should be expected during project execution.
- Pay is hourly with overtime and is commensurate with qualifications and experience.