Senior Quality Engineer

We are seeking a highly motivated individual to join us as Senior Quality Engineer at our El Segundo location. Reporting to Kite's Associate Director, Quality Engineering, you will interface and build strong partnerships with other parts of site organization.

Job responsibilities include QE oversight of site processes related to cGMP such as Commissioning, Qualification and Validation (CQV), Computer System Configuration Management and Computer System Validation (CSV). The position will ensure compliance with Kite's corporate procedures and all applicable regulatory guidelines as well as Quality oversight of commissioning and qualification of Kite's manufacturing site, providing guidance and support to the site validation group tasked with implementation of new equipment and manufacturing suites.

Responsibilities include (but are not limited to):

- Quality oversight of site CQV in collaboration with Validation, Engineering and external partners
- Quality oversight of computer system validations.
- Ensure process control and validation requirements in accordance with company procedures.
- Lead and/or support risk analysis activities. Demonstrate proficiency in applying various risk management and risk mitigation tools and practices.
- Ensure periodic reviews of Risk Management Reports are performed according to schedule.
- Evaluate product/process data (e.g. process and/or product changes, deviations, CAPAs, complaints, etc.) for their impact to the current quality risk management files.
- Author and review site quality risk management plans, reports, and risk assessments and supporting technical documents such as validation documentation and change control
- Support regulatory inspections and audits
- Apply Statistical methods and process excellence tools to evaluate qualification data.
- Lead/Support continuous improvement activities and projects within site's Quality Organization
- Contributes to root cause investigations using various problem-solving techniques and tools, and assesses effectiveness of corrective actions.
- Support vendor qualification and compliance audits
- Communicate effectively at all levels within Quality, as well as cross functionally with departments
- Perform other duties as assigned.

Qualifications:

- Bachelor's degree in technical discipline (Biology/Chemistry/Microbiology/Engineering or related field) with a strong knowledge of Quality Engineering /Scientific Method and Techniques and 7 years of experience in a pharmaceutical or FDA regulated environment.
- Knowledge of Quality Systems and pharmaceutical regulatory requirements (ICH8, ICH Q9, ICH10 GAMP5, 21CFR 11/210/211)
- Experience with Automation, Equipment, Facility and Utility IQ/OQ/PQ/PV
- Knowledge in computer System validation in a GMP environment
- ASQ Quality Engineering Certification, Green Belt Certification Preferred.
- Strong Knowledge of Change Control Practices
- Strong written and verbal communication skills
- Strong Analytical and Statistical skills
- Experience with Quality Audits and compliance initiatives.
- Ability to function efficiently in a diverse, fast paced, changing environment.
- Ability to excel in an environment that embraces teamwork, change, risk-based decision making and flexibility.
- Self-motivated to take actions, and have excellent written and verbal communication skills.

Kite is a biopharmaceutical company engaged in the development of innovative cancer immunotherapies with a goal of providing rapid, long-term durable response and eliminating the burden of chronic care. The company is focused on chimeric antigen receptor (CAR) and T cell receptor (TCR) engineered cell therapies designed to empower the immune system's ability to recognize and kill tumors. Kite is based in Santa Monica, CA. For more information on Kite, please visit www.kitepharma.com. Sign up to follow @KitePharma on Twitter at www.twitter.com/kitepharma.

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