Senior Director of Clinical Quality Assurance

Kala is an emerging pharmaceutical company on the verge of commercialization. We are seeking a Senior Director of Clinical Quality Assurance to lead the CQA function in Quality Operations. This is an opportunity for the right individual to join Kala at a time where he or she will be able develop our CQA function to reflect best practices. Our ideal candidate will partner with the Clinical Operations department to assure that our clinical studies meet or exceed all regulatory expectations. This individual will report to our Waltham, office from a reporting relationship perspective, but can be located anywhere in the US where travel options are easily accessible. Come join an experienced and highly motivated team.

Key Responsibilities for this role will include:

- In partnership with Clinical Operations, design and implement a risk-based Clinical Quality Assurance Management System
- Assure through audits that non-clinical CROs, clinical CROs, clinical sites and supporting services are operating in compliance with company's quality program, regulations/guidelines and SOPs and are acceptable for performing clinical studies and related services.
- Assure compliance with applicable worldwide clinical study regulations and guidelines (e.g. FDA, EMA, ICH).
- Act as a strong technical resource to resolve GCP/GVP issues based on knowledge of regulations, guidelines, and relevant SOPs
- Participate in the upgrade of the Quality System and procedures for multiple clinical development candidates and commercial activities
- Lead preparations for clinical operation inspections.

Our ideal candidate will have:

- Fifteen plus years of direct experience in GCP Quality Systems and oversight of drug development lifecycle, clinical research, clinical study monitoring, or pharmacovigilance.
- A minimum of five years of previous clinical QA leadership experience.
- Bachelor's degree in life sciences or related fields.
- Expertise in GCP regulations and guidance of Health Authority and ICH.
- Experience in regulatory inspections.
- Must have strong written and oral communication skills.
- Proven track record demonstrating strong leadership skills.
- Strong written and verbal communication skills.
- The flexibility and desire to travel from 50-75% of their time. Our clinical sites and clinical operations functions are located throughout the US and the expectation is that this individual will spend the majority of his or her time visiting these locations.

If you are interested in applying for this role, please send your resume directly to Careers@Kalarx.com ***and include the job title in your subject line.***

About Us:

Kala is a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary mucus-penetrating particle (MPP) technology, with an initial focus on the treatment of eye diseases. Kala has applied the MPP technology to a corticosteroid designed for ocular applications, resulting in two lead product candidates. The product candidates are INVELTYS™(KPI-121 1%) for the treatment of inflammation and pain following ocular surgery, for which we have submitted a NDA, and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, which is currently in Phase 3 clinical development.