Senior Manager of Clinical Quality Assurance

Kala is an emerging pharmaceutical company on the verge of commercialization. We are seeking a Senior Manager of Clinical Quality Assurance (CQA) 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. Come join an experienced and highly motivated team.

Key Responsibilities for this role will include:

- Partner with Clinical Operations to design and implement a risk-based a comprehensive clinical quality assurance program
- Review and approve Clinical Operations SOP's and related documents
- Create/revise SOPs and related documents for Clinical Quality Assurance activities
- Perform internal audits of Clinical Operations and Investigative Product development and manufacturing activities
- Participate in the selection and qualification of CROs and service providers
- Conduct external audits of non-clinical CROs, clinical CROs, clinical sites and supporting service providers using a risk-based approach to assure that they are operating in compliance with SOP's and clinical study regulations and guidelines (e.g. FDA, EMA, ICH).
- Act as a resource to resolve GCP/GVP issues/deviations based on knowledge of regulations, guidelines and SOPs
- Participate in the upgrade of the Kala's Quality System and procedures for the management of clinical development candidates and commercial activities
- Lead the preparations Clinical Operations for regulatory inspections. Act as the host for regulatory inspections of Clinical Operations
- Approve Investigative Product Labeling and Packaging specifications and the Master Labeling and Packaging Batch Record
- Review Investigative Product Batch Records and determine if the product is acceptable for use in clinical studies
- Participate in the review of product complaints

Our ideal candidate will have:

- 10 years of experience in the Pharmaceutical industry with most of that in the clinical stage of several product's life cycle.
- 5 years of experience specifically in the area of clinical quality assurance including the conduct of audits at CROs, clinical sites and other service providers
- Bachelor's degree in life sciences or related fields.

Experience in regulatory inspections.

- Certified Quality Assurance Auditor
- Strong written and oral communication skills.
- Proven track record in conducting audits .
- Flexibility and desire to travel approximately 20% of the time. Our clinical sites and clinical operations functions are located throughout the US.

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.