Senior Manager of Quality Assurance

Kala is an emerging pharmaceutical company on the verge of commercialization. We are seeking a Senior Manager of Quality Assurance. This is an opportunity for the right individual to join Kala at a time where significant growth is occurring and the development of a scalable quality assurance system is key. He or she will help develop processes and procedures that reflect best practice and provide assurance that the products Kala releases to the market meet Kala's quality standards and FDA regulations. The Senior Manager will work closely with the Manufacturing and Supply Chain department to assure that our products are available to meet customer needs. Come join an experienced and highly motivated team.

Job Responsibilities:

- Support QA functions related to GMP activities (e.g., cGMP manufacture of clinical supplies and commercial product
- Perform batch record review for products manufactured by Contract Manufacturing Organization (CMO)
- Determine the disposition of drug product, intermediate and raw material batches
- Review and approve Master Batch Records
- Perform audits of CMOs
- Review and approves deviation reports.
- Tracks quality investigations and CAPA to ensure closure
- Review and approve change control documents received from CMOs
- Review product complaints and coordinate complaints investigation with CMO
- Review and approve validation protocols and reports
- Create edit, review and approve SOPs

Our ideal candidate will have:

- Ten plus years of experience in the pharmaceutical industry and Quality Systems
- A minimum of five years of QA experience
- Bachelor's degree in life sciences
- Experience in regulatory inspections
- Strong written and verbal communication skills
- The flexibility to travel from 10-20% of their time to Kala's contract manufacturing sites
- A minimum of three years of experience working in companies that have an outsourced/ virtual business model
- Experience reviewing and approving batch records, associated deviations and CAPAs to determine the disposition of the batch of drug product and intermedites
- Experience reviewing and approving validation protocols and reports
- Experience performing audits of current manufacturing organizations

- Experience managing product complaint investigations

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.