



## Senior Manager of Quality Systems and Administration

Kala is an emerging pharmaceutical company on the verge of commercialization. We are seeking a Senior Manager of Quality Systems and Administration to establish our Quality System's foundation and strategy moving forward. This is an opportunity for the right individual to join Kala at a time where he or she will be able to build our Quality Systems to prepare Kala for our significant future growth. Our ideal candidate will have the opportunity to participate in the selection, validation and implementation of our Quality Management System. Come join an experienced and highly motivated team.

Key Responsibilities for this role will include:

- Lead the project of the selection, validation and implementation of our QMS
- Provide the ongoing management and administration of the Quality Management System (QMS) processes.
- Ongoing system owner of both our Controlled Document Management System and Training System
- System administrator and Super-User for the following quality processes: Change Control, Quality Issues, CAPA, Audits and Complaints.
- Coordinate user training for the Quality Management System (QMS) processes.
- Coordinate the preparation of Annual Product Reviews and Annual Reports

Our ideal candidate will have:

- Bachelor's degree in systems, life sciences or related fields
- Ten plus years of direct experience in managing electronic document management and training systems.
- Experience managing and using paper-based and electronic quality management systems (EQMS) for change control, quality Issues, CAPA, audits and complaints.
- Effective at partnering with leaders and subject matter experts to design systems that meet business needs and ensure ongoing regulatory compliance
- Experience in regulatory inspections.
- Experience authoring and reviewing batch records, standard operating procedures (SOP), training materials, specifications, annual product reviews and FDA submissions.
- Experience delivering classroom and structured OJT training programs, including user training for document management, training management and other quality processes.
- Strong written and verbal communication skills.
- Proven track record demonstrating strong leadership skills.
- Detail oriented; able to coordinate tasks that cross multiple systems and areas.

**If you are interested in applying for this role, please send your resume directly to [Careers@Kalarx.com](mailto: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.*