Director of Global Regulatory Affairs, CMC

We are seeking a highly experienced Director of Global Regulatory Affairs, focused on our CMC capabilities. Our ideal candidate must be experienced in collaborating with teams and individuals in a matrix environment. This individual must be accomplished at creating submission strategies to support pre- and post-approval CMC (Chemistry, Manufacturing and Controls) documents for the NDA/MAA. We are seeking an an expert with a deep understanding of the complex regulations governing changes to the product.

Kala is an emerging pharmaceutical company on the verge of commercialization. This is an opportunity for the right individual to be a part of a high growth small biotech.

Key Responsibilities for this role will include:

- Developing and executing successful regulatory CMC strategies for new products.
- Author, prepare, and compile high quality CMC regulatory submissions (IND, NDA, BLA, MAA, CTA, IMPDs, annual reports, etc.)
- Prepare responses to regulatory authorities, review and author CMC regulatory agency submission materials
- Perform CMC regulatory assessments for potential new products

Our ideal candidate will have:

At minimum, you must possess a advanced degree in a Life Sciences discipline, 8+ years of Global Regulatory CMC pharmaceutical industry experience, and possess a strong biopharmaceutical background with high achievement in the regulatory affairs CMC function. Experience with sterile aseptic suspensions/solutions and ophthalmology experience preferred.

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.