Job Title: Quality Assurance Manager

General Job Summary:

Perform a variety of activities to ensure compliance with applicable regulatory requirements and facilitate the management of third-party contract manufacturing organizations. Participate in the design, establishment and maintenance of programs and processes that ensure quality products and compliance with current Good Manufacturing Practices (cGMPs) for pharmaceutical, biotech and drug/device combination products.

Duties include but are not limited to:

- Author, edit, review, and approve policies, SOPs, and guidance documents. Manage and administer processes within the Zogenix Quality System.
- Review supplier/manufacturer and testing documentation including validation/qualification protocols, batch records, and other technical documents. Support final review and release of material produced at contract manufacturers.
- Collaborate with functional groups and contract manufacturers to evaluate and address complex issues such as deviations, technical complaints, corrective and preventive action (CAPA) and failure investigations. May lead or coordinate investigations and corrective and preventive action (CAPA) recommendations related to products.
- Lead or assist compliance audits (GMP, GLP, GCP, Internal and Supplier/External)
- Work with R&D as QA representative during new product start-ups, and identify routine checkpoints for new products and processes.
- Contribute to the completion of CMC sections of regulatory submissions
- Assist in the design and execution of cGMP training to ensure compliance with regulatory requirements.
- Provide Quality oversight for the labeling, packaging, storage, and distribution of clinical trial materials.
- Provide support for other Zogenix product development and QA programs.

Requirements:

Bachelor’s or Master’s Degree in a relevant scientific discipline with 5+ years demonstrated QA experience in a pharmaceutical or biotech company. Prior compliance work with sterile product, aseptic manufacturing processes, or drug/device combination products is highly desirable.

- Must have an understanding and application of FDA regulations and guidances, QA principles, concepts, industry practices, and standards.
- Demonstrated ability to develop, communicate and influence solutions to complex problems.
- Applies knowledge of current Good Manufacturing Practices (cGMPs) on a daily basis.
- Exercises judgment within well defined and established procedures and practices to determine appropriate action.
- Shows strong initiative and independence. Able to perform routine work and fulfill responsibilities with little or no additional instruction.
- Detail-oriented with good organization and time management skills.
- Strong interpersonal and verbal/written communication skills required.
- Ability to effectively participate and contribute on multi-disciplinary teams.
- Must be able to travel domestically and internationally (10-25%).