Position: Manager, Quality Assurance - GMP

Reports to: Director, Quality Assurance

Location: San Francisco office

Primary responsibility for day to day quality assurance systems and activities related to GMP compliance of Apellis' Contract Service Providers (CSPs) and San Francisco site. Assures finished products conform to regulatory and company standards and satisfies GMP regulations. Works closely with Director of QA and with CSP partners to ensure quality systems are adequate and product meets Apellis' quality standards. Position includes review and approval of Quality Management System documentation, batch record review, and batch disposition. Monitors CSP documentation for trends, identifies CAPAs, and recommends remediation plans. Lead investigations and resolve potential product quality issues to improve efficiency. The Manager will support creation of global quality management system. Assist in audits of CSPs. Plan, organize and prioritize work activities based on goals and objectives for QA.

Key Responsibilities:

- Perform Quality Assurance activities associated with clinical development and commercial GMP for drug substance and drug product manufacture.
- Provide quality and compliance oversight to GMP supply chain.
- Responsible for disposition of drug substance and drug product for global administration.
- Accountable for ensuring drug substance and drug product is dispositioned to meet Apellis' timelines; including labeling and packaging records.
- Ensure products conform to specifications and satisfies GXP regulations
- Actively work with Technical Operations and CSPs to manage receipt, review and approval of documents provided by CSPs.
- Establishes and oversees organized filing of CSP documentation
- Participate in various cross-functional projects as needed and appropriate
- Formulates and recommends quality assurance (QA) policies and programs
- Trend and evaluate CSP documentation for CAPA and remediation
- Assist in conducting CSP audits
- With the Director of QA, provide guidance to personnel performing and reviewing deviation investigations, CAPAs and change controls.
- Responsible to use risk management, investigational techniques, root cause analysis and quality concepts in the identification and evaluation of compliance risks

Qualifications:

Bachelor's degree in life sciences or equivalent science

8-10 years of progressive experience in cGMP Quality Assurance and working with CSPs

The ideal candidate has passion for learning, creating, relating, and communicating with cross functional teams.

Working Conditions:

Will work from the Company's San Francisco Bay Area office, with additional travel as required to oversee the virtual development and manufacturing network (estimated at 15%).

Apellis is…

A clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

Visit **http://apellis.com/about.html** to learn more.

EEO Statement:

Apellis is an equal opportunity employer and complies with all applicable federal, state and local fair employment practices laws. Apellis strictly prohibits and does not tolerate discrimination against employees, applicants or any other covered persons because of race, color, religion, creed, national origin or ancestry, ethnicity, sex (including pregnancy), gender (including gender nonconformity and status as a transgender or transsexual individual), age, physical or mental disability, citizenship, past, current or prospective service in the uniformed services, genetic information, marital status, AIDS/HIV status, smoker/nonsmoker, and occupational pneumocononiosis or any other characteristic protected under applicable federal, state or local law.