Job Description

Job title	Manager/Director, CMC Quality
Department	Quality
Employee Type	Full Time
Working Location	San Diego, California
Report to	Vice President, Quality

Summary

- Ansun Biopharma, Inc. is a clinical stage biopharmaceutical company developing drugs for unmet medical needs. The individual will ensure cGMP compliance of contract manufacturers and testing laboratories, cooperate with QA/QC personnel at contractors and internal stakeholders to meet manufacturing, testing, and project timeline.

Primary Responsibilities

- Participates in activities related to analytical method and process transfer, verification or validation to ensure cGMP compliance of contract manufacturers and testing laboratories.
- Reviews and approves internal technical documents (such as stability study reports) to ensure accuracy and compliance with applicable Quality requirements.
- Reviews and approves documentation associated with GMP activities at contract manufacturers and testing laboratories. These include but are not limited to laboratory methods, testing records, master batch records, raw material and product specifications, method validation protocols and reports, process validation protocols and reports.
- Evaluates the effectiveness of Contractors' quality systems by conducting effective audits for cGMP compliance, issuing audit reports, and tracking Contractor's response.
- Assures the quality of Ansun's product by reviewing and approving Contractors' change controls, deviations, nonconformances, and out of specification investigations.
- Leads or assists internal and external quality audits to ensure that studies/operations are conducted in accordance with Ansun's protocols/procedures, industry guidelines, applicable regulations.

Qualification / Education / Experiences / Skills

We are looking for a flexible, detail-oriented team player with the ability to manage multiple tasks, produce quality work and consistently meet deadlines. The successful candidate will possess:

- Minimum BA/BS in life science related field
- 5 + years experiences in biopharmaceutical industry with at least 3 years of GMP Quality Assurance experiences
- Experiences in cGMP auditing, method and/or process validation
- Demonstrated sound decision-making and problem-solving capabilities based on facts, data, and risk management principles

- A strong work ethic and a “can-do” attitude with proven track record of managing multiple responsibilities with a sense of urgency

Ansun is an Equal Employment Opportunity/Affirmative Action Employer:
Minority/Female/Disability/Veterans/Sexual Orientation and Gender Identity.