Job Description

Job title	Manager/Director, Clinical Quality Assurance
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

- Establishes, refines, implements, and maintains Clinical Quality Assurance systems, processes and procedures in accordance with regulatory requirements and ICH guideline, including but not limited to creating SOPs
- Develops and executes a quality oversight program to ensure the compliance of clinical operations
- Leads the vendor evaluation process and vendor qualification program as it relates to clinical operations through on-site audits and on-going monitoring of compliance to regulations and company policies.
- Participates in the review and approval of clinical trial materials such as Clinical Protocol, Pharmacy Manual, Clinical Investigator's Brochure, etc.
- Manages the internal audit process of clinical operations including execution, report writing, and issue management
- Ensures appropriate corrective and preventive actions (CAPAs) are completed in a timely manner. Escalates issues of critical noncompliance and/or lack of urgency in remediation to senior management.

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
- 10 + years experiences in biopharmaceutical industry with at least 5 years of Clinical Quality Assurance experiences
- Demonstrated in-depth experience of establishing, refining, and operating Clinical Quality Assurance related systems in the Biotechnology industry.
- Experiences in GCP auditing and vendor qualification
- Experiences in writing SOPs

- 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.