Position: Senior Director, R&D & Clinical Quality Assurance
Manager: SVP, Chief Quality Officer
Department: Technical Operations
Location: Bay Area, CA

JOB SUMMARY:

- Senior Director R&D and Clinical Quality Assurance (CQA) is responsible for providing leadership, strategic vision, and efficient execution in managing compliance related to Good Clinical Practices (GCP's), Good Laboratory Practices (GLP's), Good Pharmacovigilance Practices (GPVP's) and other related activities to deliver on the client's clinical goals.
- The successful candidate will be a charismatic leader with strong critical and strategic thinking skill to establish and oversee R&D, Preclinical, Clinical and Pharmacovigilance QA activities associated with cell and gene therapy products. Such products include recombinant Adeno-associated Viral Vectors (rAAV), gene-modified T cells and gene modified hematopoietic stem cells including technology platforms for ZFP genome editing, Adeno-associated Virus (AAV) gene therapy and autologous & allogeneic CAR-Tregs.
- This is an exciting opportunity for someone who has the expertise to successfully lead this function and partner with Clinical Development and Clinical Operations, R&D and Pharmacovigilance organizations globally to provide strategic GCP, GLP and GPVP compliance oversight. Effective communication and collaboration with internal and external stakeholders are a key requisite in this position.

ESSENTIAL FUNCTIONS:

- Develop, implement, and maintain GCP/GLP/GPVP quality oversight systems through establishment of an integrated Quality system and development of procedures that follow 21 CFR Part

50, 56, 58 and 312 along with ICH E6 and other relevant guidance documents. Drive a robust risk-based vendor management program. Oversee audit plans and activities, actively leverage audit outcomes/trends to achieve sustained improvement in clinical trial conduct and reporting while championing the highest standards of compliance.

- Lead the GCP, GLP, and GPVP inspection management program, including inspection readiness activities, inspection conduct, and preparation of responses to health authorities with a focus on data integrity.
- Lead the client'Pharma's Clinical QA function while promoting a culture of quality by collaborating across all departments and levels of management to accomplish company objectives and represent Clinical Quality.
- Maintain CQA compliance for ongoing and planned clinical trials.
- Directly interface with Clinical Development and Clinical Operations for GCP audits of internal processes. Promote collaboration to ensure all systems, processes, and their outcomes comply with applicable international and national standards, regulations, and guidelines.
- Collaborate and work closely with the R&D team, study directors and animal sites to effectively and efficiently set up the overall GLP oversight programs to ensure compliance with US, French and other regulatory jurisdiction requirements.
- Partner externally to perform effective audits of vendors (CROs), investigator/clinical sites, and ensure documents are tracked and maintained within standards (e.g. Trial Master Files, Clinical Study Reports, Protocols, etc.).
- Work with Clinical Operations and Regulatory Affairs to review IND and NDA submissions to ensure data and documents meet GCP guidelines. Perform QC checks of relevant clinical documents and regulatory dossiers, e.g., Investigator's Brochure, CRF, Clinical Study Reports and non-clinical/clinical sections in the IND/NDA/BLA/MAA submission to ensure data integrity and accuracy.

- Work with Clinical Operations and Pharmacovigilance to develop a robust and integrated risk management program in accordance with ICH E6 (R2), including systems and processes associated with product complaints.
- Work collaboratively with GMP QA Operations teams to ensure manufacturing and packaging of clinical materials meet study and trial requirements, and with QC to ensure testing and stability is initiated compliantly and tested on time.
- Evaluate quality events, incidents, queries, and complaints and perform risk analysis on any GCP violation reported from the clinical site or CROs (including CTM service provider), take actions to remediate, and communicate to senior management on the overall compliance status.
- Perform GCP and GLP training of internal company employees.
- Planning, coordination, control, and continuous improvement of processes and systems to assure the quality & compliance of clinical studies. Provide input and change management for quality improvements affecting CQA processes.
- Create, maintain, and revise department SOPs and documents that support the Quality Management System.
- Lead the GCP, GLP, and GPVP inspection management program, including inspection readiness activities, inspection conduct, and preparation of responses to health authorities.
- Assess new and emerging regulations and applies in a fit for purpose manner to the client's Quality Management System and practices.
- Represent R&D & clinical QA and provide quality updates as required at all levels of the organization.
- Provide leadership and strategy in spear heading Quality initiatives in line with company objectives.
- Other related duties as assigned.

EDUCATION, EXPERIENCE AND SKILLS REQUIREMENTS:

The ideal candidate for this position will have demonstrated in-depth experience of establishing and managing R&D and CQA functions in compliance with GCP, GLP and GPVP applicable regulations.

- Master's degree or equivalent in a science or health care field and significant experience in an FDA-regulated environment. Minimum of 15 years of experience in the pharmaceutical industry with a GCP focus, ideally covering all clinical phases through commercial drug product, with at least 5 years in a GCP quality/compliance role.
- Broad knowledge of clinical processes and procedures, electronic documentation systems, and GCP, GLP and GPVP regulations and guidance with demonstrated effectiveness in maintaining CQA control processes for compliance with regulations.
- Experience conducting quality audits of CROs and Investigational sites.
- Proven experience handling confidential and sensitive information with the ability to exercise discretion and show good judgment; honesty, integrity, and trust building behaviors in all dealings is essential and required.
- In-depth knowledge of FDA and ICH regulatory requirements. Experience with EMA and WHO regulations a plus.
- Demonstrates initiative and proactively provides collaborative support to the clinical team as a credible communicator. Must have excellent customer-service orientation, high degree of professionalism, and ability to work with limited direction to follow through with specific tasks.
- Continuously demonstrates a positive, 'can do' and service-oriented attitude.
- Excellent interpersonal, verbal and written communication skills with commitment to accuracy. Ability to communicate and work independently with scientific/technical personnel.
- Skilled in developing collaborative internal and external relationships with experience in building teams, through coaching and development.

- Strong PC experience and demonstrated proficiency in MS Office (Outlook, Word, Excel, PowerPoint).
- Ability to think critically and demonstrate troubleshooting and problem-solving skills.
- Self-motivated, detail-oriented and comfortable in a fast-paced small company environment with minimal direction and able to adjust workload based upon changing priorities.
- This position requires travel up to 25%.

An equal opportunity employer

The above reflects management's definition of essential functions for this position but does not restrict the tasks that may be assigned. The above duties are representative only; management may assign or reassign duties and responsibilities to this position at any time.