Quality Assurance Manager

Genezen Laboratories is a CDMO providing viral vector development and manufacturing services to biotech clients in the fields of cell and gene therapy for use in Phase I and II clinical trials. We are looking for a regulatory/quality expert to support the organization by establishing quality systems for all phases of the organization.

Job Description:

This position will hold a key role in collaborating with all sections of the organization including the client quality teams, external suppliers, external regulatory agencies and technical operations. Additionally, this role will help build scalable QA systems as the organization continues to grow. This position reports to the President of Genezen Labs and to the CSO to define day-to-day priorities and workflows. The position will be responsible for direct reports.

Essential Duties:

- Ensure facility is in compliance with current ISO and GMP standards (cGMP)
- Develop quality systems including a robust and on-going quality improvement system compliant with GMP and applicable to biologic products used in clinical trials conducted under an Early Phase (I/II) IND. Maintain knowledge of global regulatory requirements for the Viral vector manufacturing processes and facility
- Responsible for authoring quality lifecycle management documents of facilities, processes and equipment and using appropriate quality systems for implementation and maintenance
- Oversee all aspects of QA operations within the organization, including but not limited to batch record review, QA support on floor, material release, deviation investigations, CAPAs, change controls, customer quality support, SOPs. Review master batch records, product labels and all product specific documents
- Responsible for editing, reviewing and approving installation, operation and performance qualification (IOPQ) protocols and reports. Responsible for approving preventive maintenance, calibration and work orders
- Work with IT to ensure software validation is performed as needed: reviewing, approving protocols and participating in test scripts
- Review and approve raw material specifications
- Approve and release raw materials for internal manufacturing and testing
- Release viral vector product batches
- Interact with the quality team and internal stakeholders to support the development, manufacturing, testing, packaging and release of viral vector products as needed.
- Manage internal quality improvement initiatives: evaluate internal processes, suggest/design/implement improvements, create/revise relevant SOPs
- Foster a Quality mindset throughout the company by ensuring consistent, risk-based and innovative thought processes are employed to advise and make decisions

- Manage problems of varied scope using a high degree of prudence and risk-based decision making
- Manage several Quality Associate direct reports
- Additional duties as assigned

Education:

ASQ Certification
BS in Biologic or Project management related field

Experience:

Required:

5 years Quality Professional in Pharmaceutical and Biological Manufacturing
3 years Quality Systems and Cleanroom Quality Management

Preferred:

3 years Early Phase Biologics Manufacturing Quality Management
Experience with Phase I/II IND clinical trials

Skill Set:

Preparing and submitting a Drug Master File (DMF) in support of INDs or NDAs
cGMP manufacturing (Biologics experienced preferred)
Proficiency in quality oversight of all systems supporting compliance with ISO 14644-.
Proficiency in quality oversight per 21CFR 210,211 as applicable to products for clinical trials conducted under an early phase IND (Phase I/II)
Demonstrated ability to develop quality systems and a quality management plan

Salary Range: $85,000 - $105,000

Candidates interested in this position should contact:

info@genezenlabs.com

Please include the name of the position that you are applying for in the subject line of your email.

Genezen LABORATORIES