About Capsida Biotherapeutics Therapeutics

We are a fully integrated AAV engineering and gene therapy company poised to create the next generation of innovative genetic therapies, with life-changing potential for patients with grievous unmet medical needs.

We leverage our proprietary high-throughput AAV engineering platform to create viral vectors with cell-type and tissue level specificity, overcoming many of the biological limitations of early gene therapy efforts. Combined with our in-house preclinical and manufacturing expertise, we are positioned to create the next generation of AAV delivered gene therapies, dramatically changing the lives of patients.

We are founded on the idea that diverse backgrounds and skill sets combine to create an environment that stimulates innovation and creativity, enabling us to grow into a leader in the AAV gene therapy space. Our leadership team is comprised of the scientific founders that developed the underlying intellectual property, and experienced industry veterans with a track record for bringing transformative drugs to market. Together with our partners, we will combine next generation engineered capsids with cutting edge gene editing and delivery modalities to bring novel medicines to patients that need them. Our research and development labs, offices, and manufacturing space are located in Thousand Oaks, CA.

The Role

Reporting to the Senior Manager, Quality Assurance (QA) the Associate/Senior Associate, Quality Assurance will be primarily responsible for the creation, implementation, and assessment of quality systems, procedures, and records to support compliant GMP operations. Responsibilities include ensuring adherence to agency regulations (GxP) and guidance (ICHQ), industry best practices, local regulations, and internal policies and procedures. This position works closely with Supply Chain, Manufacturing, Facilities, Document/Data Management, and other GxP supporting functions to ensure compliance. This position will be based in Thousand Oaks, CA.

Responsibilities

- Author, review, and approve controlled documents for the Quality organization and other GMP functional areas including SOP's, material specifications, validation protocols, and reports
- Perform review and approval of clinical production batch records
- Author, review, and approve Quality System records including Deviation, CAPA, and Change Control records including associated root cause and impact assessments

- Define, track, trend, and report quality metrics to management
- Inspect and release GMP raw materials and components against approved specifications
- Provide hands on QA support and oversight to internal staff and suppliers/contractors to ensure compliance to SOPs and relevant Good Regulated Practice (GxP) requirements
- Assist in the preparation and hosting of regulatory (e.g. FDA, EMA, DHHS, etc.) inspections, as necessary
- Support supplier qualification activities as needed
- Serve as back-up for document management
- Maintain QA archive

Requirements

- Bachelor's degree in a related scientific or technical discipline with 2+ years of hands-on experience in a QA function in a biotechnology manufacturing facility
- Knowledge of U.S. and international regulatory standards and guidelines
- Successful history working in a fast-paced team environment, meeting deadlines, and prioritization of work from multiple projects
- Highly organized with excellent analytical and critical thinking
- Excellent oral and written communication skills
- Collaborative mindset, experience working as part of a larger group to achieve scientific goals
- Excellent problem-solving skills and experience with root cause investigations and CAPA determination
- Physical Requirements: Able to frequently lift, carry or move, and position objects weighing up to 30 pounds. Able to bend, stoop and crouch to inspect materials or place labels. Consistently able to move about to coordinate work
- Thrive in a dynamic and fast-paced work environment

Preferred Qualifications

- 5 years of experience in a pharmaceutical or biotechnology setting
- Familiarity with small company start-up
- Experience in a small company, start-up, and high growth, fast-paced environment

All qualified applicants will receive consideration for employment without regard to race, sex, color, religion, sexual orientation, gender identity, national origin, protected veteran status, or on the basis of disability.

Compensation and Benefits

The well-being of our employees and their families is of the highest importance. As such, we offer a competitive salary and exceptional benefits, including generous stock options, medical, dental, vision, disability, life insurance, and significant PTO.

We are an equal opportunity employer. All applicants will be considered for employment without attention to age, race, color, religion, sexual orientation, gender identity, national origin, veteran or disability status, or any classification protected by federal, state, or local laws.

Seniority Level
- Associate

Industry
- Biotechnology

Employment Type
- Full-time

Job Functions
- Quality Assurance
- Science

Resumes can be directed to careers@capsida.com