MANAGER, QUALITY ASSURANCE

Job Summary

Quality Assurance Managers play a crucial role at Sesen Bio by ensuring that products meet certain thresholds of acceptability. They plan, direct or coordinate quality assurance programs and formulate quality control policies. They also work to improve the efficiency and profitability of Sesen Bio by reducing waste. This role is based in Canada.

The position title and level will be determined by candidate experience and accomplishments.

Responsibilities

- Represent QA and provide support to the internal development CMC teams. Interact with contract manufacturers and internal teams to resolve quality issues.
- Provide oversight for GMP Warehouse, Laboratories and Pilot Plant and associated Quality System activities.
- Provide oversight for QP activities.
- Review existing quality workflows, perform gap assessments, and assist in identifying areas for improvement.
- Write, revise and review standard operating procedures.
- Provide employee GxP training.
- Review and approve change controls, lab investigations, deviations, and proposed corrective actions and preventative actions (CAPAs) to ensure compliance with Sesen Bio procedures, cGMP and all other applicable regulations. Track and trend quality metrics.
- Perform risk assessments for deviations and complaints.
- Review and approve protocols and reports (e.g., process validation, method transfer/validation, stability, etc.) for internal and contract organizations' activities.
- Review and approve master production documentation, test methods, specifications, label masters for contract organizations.
- Review manufacturing, packaging, and labeling drug product batch records, quality control analytical data, assess completeness of change controls, deviations, and test results for timely disposition of drug products intended for human clinical use and commerce.

- Perform batch approval and release as assigned.
- May serve as QA lead on project teams, in complex quality investigations/deviations/ compliant investigations and Corrective Action/Preventive Action (CAPA).
- May serve as QA representative in coordinating with other Sesen Bio divisions and/or contract manufacturers to conduct quality investigations and identify corrective actions.
- Maintain document control and retrieval systems for electronic records and paper archives as needed.
- Conduct external audits in the US and Europe.

Qualifications

- Bachelor's degree in chemistry, microbiology, or related scientific field. M.S. is preferred.
- Possesses 7+ years of practical experience in a pharmaceutical quality assurance environment with a cGMP, compliance, analytical testing or validation focus.
- Expertise in Quality Systems and cGMP standards applicable to clinical and commercial products and AD/QC laboratory operations for biologics and large molecule products.
- Prior participation in regulatory inspections and knowledge regulations is desirable pertaining to validation of analytical methods.
- An accountable team player and leader who is detail and quality-oriented with solid understanding of quality assurance principles, systems, methods and procedures.
- Excellent attitude with excellent verbal, written and interpersonal communication, excellent judgment and multitasking skills who can adapt to changing priorities.
- Possess critical thinking skills when making sound quality decisions based on risk management and available data.
- Ability to recognize deviations from accepted practice and apply knowledge of current Good Manufacturing Practices (CGMP) on a daily basis.
- Ability to work independently and effectively coach peers in a high-paced environment with tight timelines, while maintaining accuracy and quality.
- Ability to effectively generate metrics, and present; data, findings, and improvement initiatives/projects to QA and cross-functional leadership.

About Sesen Bio

We are passionate in our commitment to save and improve the lives of patients. Sesen Bio is a late-stage company developing fusion protein medicines. In December 2019, the company initiated the BLA submission for Vicineum™ to the FDA under rolling review. We are looking for people who share our passion for innovation and saving and improving lives. Are you one of them?

Sesen Bio is proud to be an Equal Opportunity Employer. Our goal is to have a diverse workforce. We do not discriminate on the basis of race, age, color, religion, national origin, gender, sexual orientation, gender identity or expression, veteran status or disability or any other status protected under federal, state or local law. All employment is decided on the basis of qualifications, merit and business need.

For the safety of our employees and communities in response to COVID-19, Sesen Bio has implemented a temporary work from home policy. All interviews are conducted virtually at this time.