RAFAEL Pharmaceuticals, Inc.
"To Save A Life Is To Save A Universe"

1 Duncan Drive
Cranbury, New Jersey 08512
Tel: (609) 409-7050
Fax: (609) 409-6035

Date: May 3, 2019

Position: Director of Quality Assurance

Job Description

OBJECTIVES:

The Director of Quality Assurance is responsible for leading and managing all quality assurance functions and activities.

- This position is for a high level, experienced quality assurance professional to serve as a subject matter expert and point of contact for Rafael Pharmaceuticals quality assurance. The candidate must have deep and broad expertise in pharmaceutical quality assurance, quality systems and eQMS. The candidate will leverage their direct quality assurance experience to ensure the GxP quality process is in place at Rafael Pharmaceutical.

ACCOUNTABILITIES:

Quality Assurance Subject Matter Expert

- Oversee and manage all Quality Assurance functions
- Ensure that GxP quality processes and competencies are in place to drive a culture of compliance and collaboration
- Complete Implementation and support eQMS system
- Lead preparedness for and conduct of health authority inspections. Establish and maintain positive relationship with FDA and other regulatory authorities.
- Lead the development of pharmaceutical quality systems – aligning policies, processes and procedures with internal and outsourced activities
- Assure that manufacturing activities and product testing are appropriate, are conducted in compliance with company policies and procedures, and that documentation is accessible and ensures traceability/accountability
- Ensure that Quality Agreements are complete, approved and updated at appropriate intervals
- Support planning, scheduling and performing GxP audits/inspections (internal and external) to assure adherence to company SOPs and any applicable regulatory requirements
- Oversee risk assessments to determine level of compliance risk. Lead implementation of appropriate risk mitigation strategies
- Provide guidance for investigations as well as corrective and preventive action (CAPA) plans for compliance issues and/or observations
- Support development of company training programs for GxP-related procedures, practices and system requirements
- Manage process improvements for quality information management systems
- Remain current with quality management trends. Review and interpret new regulations, and ensure that Rafael quality systems evolve accordingly
- Recruit, train and mentor staff
- Perform other duties as required
- Prepare and manage department operating plans and budgets

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Documentation/Compliance

- Ensure process knowledge documents, development reports, and specifications are compliant with internal procedures and regulatory requirements.
- Assist in the development and implementation of departmental processes, procedures and policies.
- Maintain adherence to departmental and quality systems, such as SOP training records, deviations/investigations, CAPAs, and Change Controls.
- Actively contribute to the preparation and coordination of internal audits and regulatory inspections.
- Supervise / coach less experienced staff as needed.

EDUCATION, BEHAVIOURAL COMPETENCIES AND SKILLS:

- Bachelor's degree in biopharma or related field. Advanced degree in related area preferred
- Must have a minimum of 10 years of experience in pharmaceutical/biotech industry with increasing responsibilities, including 5+ years leading a Quality function for both development and commercial activities
- Experience overseeing product approval (NDA or BLA) essential; i.e., transition from product development to commercial quality systems and operations
- Experience establishing and/or enhancing development and commercial GxP quality infrastructure and systems compliant with U.S. and international requirements. Successful track record managing U.S. and international pre- and post-approval inspections
- Extensive knowledge of GMP, GCP and GLP including 21 CFR Part 11
- Proven track record in establishing eQMS
- Expert knowledge of quality risk assessment and management methodologies, including successful application and risk remediation
- Strategic thinker, able to integrate complex business considerations in formulating a quality approach
- Strong management and interpersonal/communication skills. Prior success in working effectively with senior scientific, medical, commercial and operations staff
- Authors/reviews quality documentation, such as protocols, validation reports, methods, technology transfer reports, and scientific investigation reports, as well as technical reports needed to support regulatory filings.
- Apply knowledge and direct experience managing the life-cycle of the development and commercial projects.
- Apply QbD approach to define the design space as appropriate

LICENSES/CERTIFICATIONS:

- PMP Certification is a plus
- ASQ or similar Quality Certification is a plus

TRAVEL REQUIREMENTS:

- Ability to travel to various meetings or client sites, including overnight trips. Mostly domestic, but some international travel may be required.
- Position requires up to 10% domestic and international travel.