Position Title: *Associate Director/Director GMP Quality Assurance*

Department: *Regulatory Affairs/Quality/Technical Operations*

Reports To (title): *Sr. Director Regulatory Affairs and Quality Assurance*

Location: *King of Prussia, PA*

Date: *9/28/17*

☒ Exempt ☐ Non-Exempt

Summary of Position:

Under the direction of the Senior Director of Regulatory Affairs & Quality Assurance (QA), the Associate Director/Director of GMP Quality Assurance is responsible for maintaining company Quality Systems related to clinical and commercial development/manufacturing/testing with focus on the drug product and analytical activities. Specifically, responsible for ensuring that investigational and commercial drug products are manufactured, tested, analyzed, packed and released for use in clinical trials and/or to market in accordance with their requirement's and / or registered approvals and in compliance with the principles of cGMP. In addition, position is responsible for over-site of suppliers/contract manufacturing organizations (CMOs) through GMP investigations and audits to ensure regulatory compliance.

Position Responsibilities:

- To support execution of the Quality Management System related to document development, review and approval as applicable to ensure compliance is achieved and maintained (i.e. SOPs, complaints, deviations, investigations) with focus on drug product and analytical activities.
    - *Drug Product:*
        - Perform thorough batch record review and release in an efficient and timely manner; assure non-conformances are properly investigated and explained, and calculations are correct. Review finished product packs and batch documentation and check against registered specifications prior to market release or advising rejection of batch. Ensure Paratek release documentation for each batch is accurate and filed post release according to procedures.
        - Processing and management of change controls raised by contract suppliers. Responsible for closure of change controls, CAPAs and effectiveness checks.
        - Review drug product regulatory dossiers for conformance to source documents.
    - *Analytical:*
        - Assess and support GMP compliance for analytical topics (validation and transfer of analytical methods, setting of analytical specifications for the product filing(s)) to maintain compliance with the principle of GMP as required by regulatory filings as well regional or national laws and guidelines. This includes:
            - Review and approve protocols, reports, test methods and specifications.
            - Conduct, review and/or approve laboratory documentations

including deviations/investigations, OOS, and change controls.
- Verify analyses of experimental and stability samples are coordinated and conducted in accordance with cGMPs, company SOPs, methods and protocols.

- To develop and maintain good working relationships with other Paratek functions and with Paratek's GMP suppliers and act as the primary point of contact for GMP QA related issues with focus on drug product and analytical activities.
- Ability to audit CMOs and manage all follow-up activities. Perform and Participate in internal and external cGxP audits as required. This includes PAI readiness.
- To ensure that Quality Technical Agreements (QTAs) with Paratek suppliers are established, maintained, implemented and revised.

Candidate Requirements:

- Bachelor's degree in chemistry, biology or related discipline.
- Practical experience for at least 15 years in the Pharmaceutical industry specifically in the manufacturing/technical/QA space with at least 10 or more years of direct QA experience required.
- Good working knowledge of US cGMPs for a variety of dosage forms and preferably in the sterile environment.
- Good working knowledge in the analytical space. Good understanding of analytical method validation, pharmaceutical drug substance/drug product analytical technique and microbiological testing requirements.
- Experience working with contractors and with managing QTAs, conducting site audits, etc.
- Maintain current knowledge of local and international regulatory and legislative requirements and trends to ensure that technical support on all quality related matters is provided to the country.
- Strong analytical knowledge and experience.
- Ability to anticipate problems and devise logical solutions.
- Strong interpersonal and communications (written and oral) skills.
- Self-starter who takes initiative.

Additional Information:

- Technology needs: Microsoft Office
- Travel requirements (%): 40-50%, as needed