Position Title: ***Contractor*** *- GMP Drug Product and Analytical QA*

Department: Regulatory Affairs/Quality/Technical Operations

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

Location: King of Prussia, PA

Date: 9/26/17

☐ Exempt ☒ Non-Exempt

Summary of Position:

Under the direction of the Senior Director of Regulatory Affairs & Quality Assurance (QA), the Contractor GMP QA is responsible for providing QA and Technical support to Paratek with a focus on drug product and analytical activities. They will be responsible for ensuring that investigational and commercial 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.

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)
- 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 per procedures.
- Processing and management of change controls raised by contract suppliers. Responsible for closure of change controls, CAPAs and effectiveness checks.
- Act as QA SME for CMC related issues. Review drug product and analytical regulatory filings from a QA point of view.
- Ability to audit CMOs and manage all follow-up activities. This includes PAI readiness.
- To ensure that Quality Technical Agreements (QTAs) with Paratek drug product suppliers are established, maintained, implemented and revised.
- 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
    - Be knowledgeable about the methods supporting release of drug product
    - Provide support and communication regarding technical information and queries

Candidate Requirements:

- Bachelor's degree in chemistry, biology or related discipline or equivalent.
- Practical experience for at least 10 years in the Pharmaceutical industry specifically in the manufacturing/technical/QA space. Previous QA experience in a pharmaceutical

environment 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.
- Experience working with contractors and with managing QTAs, conducting site audits, etc.
- 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 (%): 25%, as needed