Position Title: *Director, Drug Product Manufacturing Science and Technology*

Department: *Technical Operations*

Reports To: *Vice President, Technical Operations*

Date:

_x_Exempt *__Non-Exempt*

Summary of Position:

This position is part of Paratek's new Technical Operations team responsible for ensuring a robust commercial launch and reliable supply of our new antibiotic product. The main responsibility of this position is lead all drug product manufacturing and technical service activities through scale-up, validation and on-going commercial supply. This position will be responsible for technology transfer and process improvement initiatives to support Paratek's projected growth of the product. The individual will work closely with Quality Assurance, Regulatory, Supply Operations and external third party operations to ensure all aspects of manufacturing operations and technical services are successfully executed. In addition, the individual will be responsible for establishing systems for managing process information and for data analytics used for investigations and manufacturing process optimization. This position offers an experienced individual a significant opportunity to establish best practices for technical support of cGMP manufacturing operations and packaging.

Position Responsibilities:

- Lead cross functional teams for external cGMP manufacturing of drug product and packaging activities.
- Track and coordinate project milestones related to raw materials, equipment readiness, analytical testing, process information, and manufacturing documents to initiate and complete batches per the validation/production schedule.
- Ensure that cGMP batch documentation allows the process to achieve the intended process control strategy. Ensure that the process is capable of achieving control limits and specifications.
- Investigate, identify root cause, and identify CAPA for manufacturing deviations.
- Trend process performance. Establish data analytics to serve as metrics, to assist in investigations, and as feedback for manufacturing and/or process optimization.
- Author technical reports and protocols in support of cGMP activities.
- Coordinate sampling plans for GMP batches related to lot release, stability, and characterization.
- Identify and implement opportunities to improve process performance and cGMP operations.
- Manage external vendors to ensure delivery of raw materials, equipment, or services; on time and within budget.

Candidate Requirements:

- Biochemical engineer, Chemical engineer, or Biochemistry background. Ph.D. with 3+ years experience or MS/BS with 6+ years experience in a pharmaceutical or biotechnology company.
- Demonstrated knowledge of cGMPs and experience providing technical support in a cGMP manufacturing environment.
- Experience in process development or cGMP manufacturing of parenteral and solid oral dose products.
- Demonstrated expertise in validation, commercial manufacture and packaging of parenteral and solid oral dose products.
- Proven track record leading and managing cross functional teams.
- Knowledge of data management tools and statistical process control.

Additional Information: 25% travel expectation, proficiency in Microsoft Office required.