Position Title:	*Manager/Associate Director Regulatory Affairs*
Department:	*Regulatory & Quality Assurance*
Reports To:	*Head of Regulatory Affairs*
Location:	*King of Prussia, PA*
Date:	
_x_Exempt	*__Non-Exempt*

Summary of Position:

The Manager/Associate Director Regulatory Affairs is responsible for providing regulatory expertise and strategy for investigational and marketed products. This role will provide strategic and operational regulatory support on preclinical, clinical, and CMC issues. This role will also ensure that promotional practices and materials are consistent with regulatory guidelines and law and support marketing and sales objectives.

Position Responsibilities:

- Offers strategic and operational regulatory support to preclinical, clinical, manufacturing, quality assurance and marketing departments.
- In collaboration with senior management, develops and reviews regulatory strategy for operational efficiency.
- Interprets applicable regulations and guidelines for implications to Paratek. Keeps colleagues and leadership abreast of regulatory decisions, issues, potential problems and new regulations.
- Responsible for agency submissions associated to projects.
- Responsibility for the labels for Paratek products.
- Ensures timely submission of appropriate regulatory documents to Regulatory Health Authorities
- Coordinates and solicits components of the submission from various functional areas.
- Raises major project issues to senior management for resolution and agreement.
- Work efficiently and effectively within regulatory team, fostering collaborative exchanges, and teamwork.
- Maintains a high level of professional expertise through familiarity with scientific literature and participation in training courses.
- Facilitates the development, review, and approval of promotional materials and promotional materials and marketing activities to ensure compliance to regulatory guidelines and law, and consistency with corporate policies.
- Reviews promotional material and activities for regulatory compliance, suggests revisions to ensure compliance, and approves promotional materials independently.
    - Resolves promotional related issues for team – escalating as necessary
    - Prepares background material and FDA submission for all DTC, launch, and new campaigns for preclearance from the FDA.
    - Prepares background material for all meetings with DDMAC for product team
    - Review, and approve promotional material and 2253 submissions.
    - Participates in FDA meeting preparation and attends key FDA meeting (when appropriate) that have commercial implications for product teams
- In collaboration with senior management and commercial colleagues develops a US promotional regulatory strategy for brand teams.
- Provides US regulatory input into target claims statements and target product profiles including licensing candidates, ensuring proposed claims are adequately supported by data, and will maximize the commercial potential for the US market
- Works collaboratively with the cross functional colleagues to ensure that quality and regulatory standards are considered throughout the product development life cycle
- Continually monitors the regulatory environment to maintain expertise in regulatory principles, new issues, competitive products, and implications for Paratek.

- Provide regulatory support for company booths at conferences and scientific meetings.

Candidate Requirements:

- Bachelor's degree in pharmacy, pharmacology or other life science, or equivalent experience preferred.
- Generally, has at least 7 years of related experience within a pharmaceutical company, CRO or similar organization
- Generally, has at least 4 years direct regulatory affairs experience with at least 3 years of promotional regulatory experience
- Must have experience in drug promotional review.
- Must be able to communicate comfortably and effectively with regulatory authorities.
- Must have experience effectively working in team environment.
- Must be able to independently present complex information to Paratek senior management, CROs, regulatory authorities and the medical community.
- Requires strong attention to detail in composing and proofing materials, establishing priorities, scheduling and meeting deadlines.
- Must be able to work in a fast-paced environment with demonstrated ability to juggle multiple competing tasks and demands.
- Ability to work independently, take initiative and complete tasks to deadlines.
- Proven ability to independently resolve problems.
- Strong knowledge of MS Word, Excel, PowerPoint, Project and Outlook.
- Excellent verbal and writing communication skills
- Experience in interacting with FDA review division(s) or DDMAC.
- Solid problem solving skills

Additional Information: