Position Title	
Regulatory CMC Manager/Associate Director	

Summary of Position:

Under the direction of the Senior Director of Regulatory Affairs and Quality Assurance, the Regulatory CMC Manager/Associate Director is responsible for assisting in the authoring of Paratek's regulatory CMC submissions and compiling and archiving of regulatory / Quality / manufacturing source documents. In addition, this position will be supporting the generation and QC/audit of regulatory documentation used for submission to the Health Authorities.

Position Responsibilities:

- Assist with the authoring/reviewing of the preparation and filing of regulatory CMC submissions for global development activities ultimately leading to NDA/MAA submissions/approvals. Emphasize on authoring batch analysis tables, batch pedigree tables, stability tables, and analytical procedures/validations.
- Facility and familiarity with constructing, compiling, reviewing and maintaining regulatory submissions in accordance with eCTD requirements.
- Support the generation of regulatory CMC documentation used for submission to the Health Authorities as needed.
- QC the regulatory CMC documents in accordance with Paratek standards and audit all regulatory CMC documents against site source documents/raw data. Maintain/manage all applicable source documents for each regulatory CMC submission.
- Support the regulatory team in creating/reviewing Module 1 (regional documents) as needed for marketing application submissions.
- Assist the team with tracking and completing regulatory and quality commitments.
- Management and archival of all documentation from our drug substance and drug-product contract-manufacturers including master batch records, methods and specifications.
- QC quality related documents, such as SOPs, memos to file, etc . in accordance with Paratek standards
- Perform any activities to aid QP/batch release for clinical/commercial supplies in alignment with Annex 16 requirements.

Candidate Requirements:

- Degree in scientific discipline with 3 to 5 years (manager) or 5 to 7 years (AD) CMC regulatory experience in the pharmaceutical industry.
- Ability to work and organize within electronic document management systems.
- Familiarity with batch record systems in drug product manufacture, packaging and labelling.
- Excellent written and verbal communication skills with thorough attention to detail in documentation review
- Ability to work collaboratively in a small company structure.
- Knowledgeable in EMA and ICH guidelines relevant to CMC aspects of product development and maintenance.

Key Skills and Abilities:

- Strong technical and administrative skills
- Ability to deal with problems arising and the development and execution of remediation efforts
- Regulatory, manufacturing and/or quality knowledge and experience
- Logical problem solver
- Excellent communicator with good interpersonal skills
- Good self-starter