



Position Title: Associate Director, Analytical Chemistry

Department: Technical Operations

Reports To (title): Director, Analytical Chemistry

Location: King of Prussia, PA

Date:

Exempt Non-Exempt

Summary of Position:

The Associate Director of Analytical Chemistry is responsible for the management and performance of product testing methodologies and specifications (including raw materials, intermediates, drug substance, in-process-controls, and drug products), reviewing and analyzing analytical release and stability data, and analytical deviations/laboratory issues/investigations/change controls.

Position Responsibilities:

The Associate Director of Analytical Chemistry will serve as the internal expert for all commercial testing analytical related aspects for our portfolio. This will include reviewing, analyzing and interpreting product results and providing feedback of specifications and test methods, evaluating and trending of release and stability data, and assisting in any analytical/laboratory issues/investigations and change controls throughout the commercial network. Primary role includes:

- Review and assist with establishing appropriate specifications for raw materials, drug substance, in-process intermediates, and drug products.
- Review and approve technical documentation, ensuring accuracy, clarity, and quality. This includes protocols, test reports, stability reports, technical reports, SOPs, etc...
- Review and evaluate all release and stability data to ensure compliance with established specifications for all aspects of the product and to evaluate the trending of release and stability data.
- Serve as technical lead for laboratory related investigations and provide support for process investigations as needed. Maintain compliance with cGMP regulations, and quickly resolve discrepancies. Candidate should have an understanding of how the analytical function interfaces with quality systems, such as deviations, change controls and CAPAs.
- Review and approve analytical related change controls.
- Writing and/or reviewing of regulatory CMC submissions concerning analytical activities.
- Manage the performance of external test labs and resources to support the company's commercial supply chain. Experience in outsourced manufacturing and testing programs is preferred.
- Manage the inventory and qualification of reference standards and key impurity markers for all of Paratek's commercial products.
- Proactively maintain up-to-date knowledge of current analytical and laboratory practices including a current understanding of USP/EP, cGMP regulations, ICH and FDA Guidance Documents and initiate changes to maintain compliance.

Candidate Requirements:

- Degree in Analytical Chemistry; advanced degree a plus with a minimum of 5 years experience in pharmaceutical or biotechnology industry and a minimum of 2 years experience in a quality control laboratory setting.
- Experience working with 3rd party contract manufacturing and laboratory sites (working in a virtual company).
- Extensive troubleshooting and continuous improvement skills and experience needed.
- Broad and extensive understanding of analytical techniques and testing methodologies (HPLC, GC, dissolution, spectroscopy, wet chemistry, microbiology, NMR, X-ray, etc.).
- Lean six sigma, DOE, and statistical skills and experience desirable.
- Strong verbal and written technical communication skills.
- Thorough knowledge of USP and EP raw material testing.
- Strong understanding of quality and regulatory requirements as applicable to analytical chemistry and testing of pharmaceutical, nutritional or veterinary products
- Comfortable in an environment that is changing, growing and learning. Able to shift priorities as needed and as appropriate.

Additional Information:

- Technology needs: Microsoft Office required, Minitab and/or JMP preferred
- Travel requirements (%): 15%, as needed