Quality Control Manager

Reports to: Senior Vice President, Manufacturing and Nonclinical Development

Classification: Exempt

Summary:
Coordinate and provide oversight to activities related to analytical test methods and their use for release, stability, and in-process samples at contract organizations.

Essential Functions and Job Responsibilities:

- Serve as a QC subject matter expert on various methods and technologies within the CMC team and with external partners
- Provide oversight and management of contracted cGMP QC testing laboratories
- Assist in development of specifications for starting materials, intermediates, in-process testing, drug substance and drug product, which includes providing justification of specification documents
- Review and approve cGMP method validations, transfer protocols, stability protocols and reports
- Troubleshoot potential challenges during validation and address and advise on issues such as deficiencies and discrepancies
- Manage and monitor schedules for sample analysis for release, stability and in-process testing
- Manage stability program include review and approval of CMO stability protocols, assuring compliance with the stability testing program, and review and trending of stability data
- Ensure sample testing and data approval deadlines are met
- Perform a technical review and evaluate raw data for all analytical testing
- Perform QC review of executed batch records
- Ensure method performance and sample data real time trending
- OC Lead for technical review of laboratory deviations and investigations as required
- Author, revise, and/or approve SOPs as needed
- Work closely and collaborate in a team environment with Quality Assurance, Regulatory Affairs, CMC and Research and Development teams
- Provide QC information and review regulatory filings

Minimum Qualifications:

- BS degree in a relevant scientific area with a minimum of 10 years' experience, or advanced degree with a minimum of 5 years' experience
- Applied knowledge and in-depth understanding of GMP Quality Control systems
- Applied knowledge and in-depth understanding of analytical techniques
- Analytical experience with small molecule and solid oral dosage forms is preferred
- Comprehensive knowledge of chemical and microbial analysis, manufacturing operations, GMP's and the theories and general principles behind them
- Understanding of laboratory equipment such as HPLC, ICP-MS, GC-MS, FTIR, etc.
- Demonstrated problem solving ability, interpersonal, oral and written communication skills who can work independently and in a team environment
- Experience with external CMOs and analytical laboratories is preferred
- Direct experience in authoring and review/approval of SOPs