Position: Manager/Senior Manager, Quality Control

JOB DESCRIPTION:

This position is part of team having primary responsibility for the Quality Control (QC) of compendial and non-compendial excipients, active ingredients, in-process materials and finished drug products. This individual will work internally with Quality Assurance, Pharmaceutical Sciences, Technical Operations, Regulatory Affairs and Project Management to ensure that timelines for product development, process development, manufacturing and regulatory filings are met. This individual will also oversee assigned work with external contract testing laboratories for outsourced quality control testing of excipients for supplier qualification, in-process samples to support process validation, drug substances and components to support clinical and commercial products. This position will be responsible for schedule oversight, data review, trending and tracking of raw materials, excipients and components.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Oversight of the raw material qualification program for all products development through commercial.
- Review of test results, change controls and writing and revising standard operating procedures.
- Review and approve contract analytical testing laboratories method validation protocols and reports for excipients, drug substances and components.
- Review and approval of associated deviations and Out of Trend and Out of Sepcification investigations.
- Supports the Supplier Audit Program by participating in contractor audits to assure compliance to Heron quality policies, cGMPs, and regulatory filings. Participates in audits of contract testing laboratories to ensure compliance with cGMP's and readiness for Pre-Approval Inspections.
- Identify and assist in the resolution of quality related issues that impact cGMP compliance, regulatory filings, or other risks, to Heron products.
- Collaborates with contract testing laboratories and internal groups to find solutions concerning quality issues.
- Contributes to annual product reviews for marketed products.

REQUIREMENTS:

- BS in life sciences (Biology, Chemistry, Pharmacology) with 5-10 years in Pharmaceutical Quality Control Operations with the application of cGMPs for development through commercial operations.
- Excellent oral and written communication skills in cGMP documentation.
- Experience in analytical method development, validation, optimization and transfers.
- Experience in GXP compliance audits and laboratory oversight.
- Interpersonal skills to interface and develop effective relationships with suppliers.
- Excellent team work, communication and negotiation skills in dealing with internal and external partners with the ability to lead and manage quality related projects.
- Possess technical knowledge related to typical Quality Control activities in the pharmaceutical and medical device industries.
- Thorough knowledge of GMP's and regulatory requirements.
- Up to 20% travel required.
- Understanding of parenteral drug product and drug/device combinations.

EOE

The above description is intended to describe the general nature of the job and may include other duties as assumed or assigned; it is not intended to be all inclusive or limit the duties of the position.