Analytical Chemist- JD

Your Role and Responsibilities include but not limited to,

- Perform Analytical Method Development activities
- Perform formulation analysis and conduct product characterization studies
- Identify and implement appropriate analytical methods to meet project objectives. Modify methods appropriately with minimal guidance
- Develop and validate new analytical methods with minimal guidance and Assist other laboratory staff in Analytical R&D
- Perform, Maintain and Coordinate the appropriate qualification, maintenance, and calibration of instruments and equipment. To obtain assistance or request a service call from instrument service representative when appropriate.
- Perform and support routine analytical Development within the cGMP Analytical laboratory
- Prepare and review technical reports/protocols and documents to support regulatory filings. Communicate effectively using all forms of communication (Verbal, Written documents, etc.).
- Ensure all work is documented in a clear, concise and timely manner. Documentation may include notebooks, technical reports, and Development Memos as needed.
- Work in a team atmosphere in close collaboration with the analytical, formulation, process development, clinical manufacturing, operations groups, and compliance.
- Require knowledge of GLP, GMP regulations and FDA Guidelines
- Require knowledge of troubleshooting to various analytical instruments
- Review the analytical data for completeness and correctness.
- Qualify/transfer analytical methodology to the quality control lab.
- Provide training, leadership, and supervision to junior staff.

Qualifications & Requirement:

- BA/BS Degree in life sciences with Minimum of 7 years of experience OR MS or PHD in a scientific discipline from an accredited university.
- Approximately 2 year of related experience required. A combination of equivalent education and relevant work experience may also meet these requirements.
- Good communication skills and ability to collaborate with others, ability to learn new techniques, perform multiple tasks simultaneously, keep accurate records, follow instructions, and comply with company policies
- Experience with common pharmaceutical laboratory equipment including, but not limited to: UV spectroscopy, HPLC and GC instrumentation, Dissolution testing
- Knowledge of Safety and hazardous waste requirements, cGMP & cGMP standards, standard operating procedures, approved test methods and/or protocols, regulatory requirements.
- Analytical experience in a regulated Pharmaceutical industry, fast paced GMP/FDA environment
- Must be flexible with changing business needs and perform other duties as assigned.
- Authorization to work in the United States indefinitely without restriction or sponsorship

Physical Demands/Factors:

- While performing the duties of this job, the employee is regularly required to stand. The employee is frequently required to sit, walk, talk, hear, handle or feel tools or controls. The employee is occasionally required to reach with hands and arms, stoop, crouch, climb or balance, kneel. The employee must occasionally lift and or move up to 20 pounds. Specific vision abilities required by this job include close vision, distance vision and peripheral vision.
- The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

This job description is not all-inclusive. It acts as a guideline and is subject to change over time. Additional duties may be assigned based on business needs.

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