Job Description
Quality Control Chemist II

Job Function Summary:

The Quality Control Chemist II is responsible for routine QC laboratory analysis of raw materials, in-process materials, finished products, stability and process validation. The candidate must demonstrate experience working in a cGMP laboratory and possess basic knowledge of industry regulations related to pharmaceutical manufacturing.

Core Responsibilities:

- Demonstrate competence in conducting chemical analyses according to company established Standard Operating Procedures (SOP's), Current Good Manufacturing Practices (cGMP's), Good Laboratory Practices (GLP's), FDA/DEA/OSHA regulations.
- Knowledge of regulatory guidances and compendia pertaining to laboratory analyses.
- Ability to execute SOP's, test methods, and other documents related to raw material, in-process, finished product/validation and stability testing.
- Perform routine laboratory testing such as assay, content uniformity, blend uniformity, impurities, identification, moisture, LOD, particle size, bulk/tapped density.
- Proficiency in operating the following laboratory instrumentation/equipment:
    - Analytical balances
    - pH meter
    - Karl Fischer water titrator
    - UV-Vis Spectrophotometer
    - FT-IR Spectrophotometer
    - Dissolution (Apparatus I and II)
    - HPLC/UPLC
- Knowledge of HPLC and (or) UPLC, using Empower 3 software. Must be able to analyze and interpret data from Empower 3.
- Perform basic trouble shooting of laboratory instrumentation, analysis and methodologies.
- Maintain a neat and legible laboratory notebook. Must demonstrate good documentation practices (GDP's) as required for logbooks and laboratory notebooks.
- Assist in the review of laboratory documentation and test data to ensure completeness and accuracy.
- Ability to detect and report laboratory events, OOS/OOT investigations to laboratory management.

- Participate in all training essential to job functions and assist Chemist I colleagues with basic training as determined by laboratory management.
- Ability to work with different types of chemical solvents, using proper personal protective equipment (PPE), as defined by the standard operating procedures to ensure a safe work environment.
- Complete all projects in a timely manner, to ensure Safety, Quality and Customer Service.
- Provide daily status updates on projects to the laboratory management.
- Other job duties may be assigned as needed by laboratory management.

Preferred Skills

- Competency in conducting chemical analyses
- Knowledge of USP/NF related to solid dose pharmaceutical manufacturing
- Demonstrates attention to detail
- Highly motivated individual, who demonstrates teamwork
- Strong interpersonal, writing, and multi-tasking skills
- Effective communication skills
- Competency in Microsoft Office Suite
- Ability to work under minimal supervision

Physical Requirements

- Ability to wear personal protective equipment (safety glasses, respirator, gloves, etc.)
- Ability to stand for long periods of time
- Ability to lift/carry 10-15 lbs

Education and Experience

- BS in chemistry, organic chemistry, or biochemistry, with course work in analytical chemistry
- 2 years relevant experience in an analytical laboratory