



Job Description

Quality Control Chemist III

Job Function Summary:

The Quality Control Chemist III is responsible for routine QC laboratory analysis of raw materials, in-process materials, finished products, stability and process validation. The candidate must demonstrate competence in conducting most types of physical and chemical analyses (including complex analyses) using a wide variety of laboratory equipment. Experience working in a cGMP laboratory and thorough knowledge of regulatory guidances and compendia is required. Collaboration, teamwork, accountability, and the ability to multitask are critical to a fast-paced environment.

Core Responsibilities:

- ❖ Demonstrate competence in conducting most types of physical and chemical analyses (including complex ones) according to company established Standard Operating Procedures (SOP's), Current Good Manufacturing Practices (cGMP's), Good Laboratory Practices (GLP's), FDA/DEA/OSHA regulations.
- ❖ Possess advanced knowledge of regulatory guidances and compendia pertaining to laboratory analyses.
- ❖ Ability to efficiently execute SOP's, test methods, and other documents related to raw material, in-process, finished product/validation and stability testing.
- ❖ Demonstrate efficiency in laboratory testing such as assay, content uniformity, blend uniformity, impurities, identification, moisture, LOD, particle size, bulk/tapped density, etc.
- ❖ Proficiency in operating the following laboratory instrumentation/equipment, including but not limited to:
 - Analytical balances
 - pH meter
 - Karl Fischer water titrator
 - UV-Vis Spectrophotometer
 - FT-IR Spectrophotometer
 - Dissolution (Apparatus I and II)
 - HPLC/UPLC
 - GC
 - DSC (Differential Scanning Colorimeter)

- ❖ Advanced knowledge of HPLC and (or) UPLC systems, using Empower 3 software. Thorough knowledge of custom fields/calculations/reports within the Empower 3 software. Assist other chemists with integration and processing parameters in Empower 3.
- ❖ Assist other chemists with trouble shooting of general laboratory instrumentation, analyses and methodologies.
- ❖ Maintain a neat and legible laboratory notebook. Must demonstrate good documentation practices (GDP's) as required for logbooks and laboratory notebooks.
- ❖ Perform peer review of laboratory documentation and all lab data to ensure compliance with laboratory SOPs, test methods and industry regulations.
- ❖ Assist laboratory management with laboratory events, OOS and OOT investigations.
- ❖ Train other QC chemists on various lab techniques and procedures as needed.
- ❖ Notify laboratory management of any improvements related to test methods or SOPs and assist with the appropriate document revisions.
- ❖ Author/review COAs and stability reports upon completion of associated projects.
- ❖ 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 and troubleshooting laboratory equipment
- ❖ Advanced Knowledge of USP/NF related to solid dose pharmaceutical manufacturing
- ❖ Great attention to detail
- ❖ Highly motivated individual, who demonstrates teamwork
- ❖ Strong organizational 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
- ❖ 3-4 years relevant experience in an analytical laboratory