

PrimaPharm, Inc.
Job Description

Job Title: Analytical Chemist II
Department: QC- Analytical Services & Product Development
Reports To: Director, QC - Analytical Services & Product
FLSA Status: Nonexempt
Prepared By: HR Consultant/ Director, QC - Analytical Services & Product Development
Prepared Date: 11/20/12
Approved By:
Approved Date:

Summary

This position supports the different activities within the QC – Analytical Services and Product Development department and is responsible for performing assay (enzyme kinetics) and wet chemistry work. Additionally must be able to write, revise, and follow SOP's and develop analytical methods.

1. General Duties and Responsibilities include the following. Other duties may be assigned.

Able to perform assay (enzyme kinetics) on in-process, final and stability samples using UV-VIS- Spectrophotometer.

Able to perform wet chemistry work.

Ability to perform qualitative and quantitative assays by following SOP.

Write and revise SOP's as needed.

Perform verification and validation of USP and develop analytical methods

Maintain a clean and safe work environment and follow all safety policies and procedures.

Other tasks and duties as assigned by Supervisor.

2. SPECIFIC RESPONSIBILITIES

2.1. Perform testing for raw materials, excipients, in-process testing, release testing, and part of shelf life testing to include:

2.1.1. Stability studies program

2.1.2. Assay for Ferric Subsulfate (Back up)

- 2.1.3. Assay for AstrinGyn (Back up)
- 2.1.4. pH
- 2.1.5. Osmolality
- 2.1.6. Conductivity
- 2.1.7. Specific Gravity
- 2.1.8. Color and Clarity
- 2.2. Incoming Material Receipt, Sampling and preparing of approval and release (Back up).
- 2.3. Sampling and sending samples for tests to outside contract laboratories (Back up).
- 2.4. Assist in Review / Revise of protocols and report

Accountability

Perform assay (enzyme kinetics) and wet chemistry work. Write, revise, and follow SOP's and develop analytical methods.

Feedback

Routine performance evaluations conducted by the Director of QC – Analytical Services and Product Development.

Supervisory Responsibilities

This position has no supervisory responsibilities.

Qualifications To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Education and/or Experience

Minimum BA/BS in Chemistry/Biochemistry, preferably in Chemistry or equivalent combination of education and experience. Master's preferred.

Language Skills

Ability to read, analyze, and interpret general business procedures, technical procedures, or governmental regulations. Ability to effectively present information and respond to questions from groups of managers, and employees of the organization.

Mathematical Skills

Ability to work with mathematical concepts such as probability and statistical inference, and fundamentals of plane and solid geometry and trigonometry. Ability to apply concepts such as fractions, percentages, ratios, and proportions to practical situations.

Reasoning Ability

Ability to define problems, collect data, establish facts, and draw valid conclusions. Ability to interpret an extensive variety of technical instructions in mathematical or diagram form and deal with several abstract and concrete variables.

Computer Skills

To perform this job successfully, an individual must have knowledge of database, spreadsheet and word processing software. The organization uses Microsoft Office (Word, Excel).

CERTIFICATES, LICENSES, REGISTRATIONS: List the licenses, certificates and registrations that are required to perform the essential duties of this job.

None

OTHER SKILLS AND ABILITIES:

OTHER QUALIFICATIONS:

1. Meticulous, detail oriented, punctual and willing to switch shift as needed.
2. Able to perform work under cGMP environment.
3. Able to use excel, PowerPoint and other MS Office applications.

Physical Demands 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.

While performing the duties of this Job, the employee is regularly required to sit, talk and hear; and ability to lift up to 25 pounds; and sometimes be exposed to caustic chemicals.

Work Environment The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

The noise level in the work environment is usually moderate.