Stability Coordinator

VistaPharm, Inc. - Largo, FL

Job Summary:

The Stability Coordinator is responsible for the general operation and support of the stability program, including the oversight of ongoing studies, operation & maintenance of stability chambers and related equipment, as well as development and approval of all study related protocols and reports including for all ANDA products.

Job Responsibilities:

- Responsible for the selection of annual stability batches to be included in the stability program as per regulatory requirements.
- Receives stability samples, prepare labels indicating charge-in dates, pull dates, intervals and storage conditions that are to be applied on these samples, affix labels and distribute samples to appropriate storage conditions as identified in approved stability protocols. Indicates the sample additions to the sample log residing in the stability storage area.
- Initiates stability studies in the system according to approved protocols as and when required.
- Manages distribution and pull of stability samples to and from designated stability storage conditions
- Performs a combination of sample management tasks, including labeling, preparing for shipping, transporting to labs, inventorying and disposing.
- Reviews and verifies sample paperwork against samples to ensure accuracy and communicate discrepancies. Distributes sample information and paperwork to QC laboratories and other applicable areas.
- Assists with stability studies as needed and directed. Including removal of samples from stability and verification of information.
- Ensures all work performed strictly adheres to cGMP, company and client documents.
- Handles R&D stability samples and monitors all applicable documents related to R&D.
- Assists in conducting, monitoring and reporting studies to ensure data accuracy and report quality metrics related to stability such as on time pulls, on time testing, etc.
- Yearly Inventory reconciliation for Stability Studies
- Reconciling and Disposition of extra Stability Samples
- Data entry and or review in Micro Control Solution System, Excel, and other system as necessary.
- Monitors the environmental conditions of the stability chambers.
- Initiates and/or provides support to stability related NOE’s such as for chamber environmental excursions, inventory discrepancies, laboratory OOS/OOT investigations etc.
- Creating and distributing weekly pending reports to labs for sample delivery notification.
- Conducts statistical evaluation of stability data in support of laboratory investigations or as required by Management.
- Supports the Laboratory management in any investigation related to the stability program.
- Filing/creation / maintenance of stability study record folders.
- Prepare stability summary reports including stability tables to support Annual Product Reviews, Regulatory Annual Reports and filings for Regulatory submissions.

Qualification and Requirements:

- Experience managing samples and data into regulated electronic systems.
- Excellent technical writing skills including experience with SOPs and document review processes
- Experience working with Change Control Documentation
- Experience in a regulated, GMP or GLP environment
- Strong computer, scientific, statistical analysis and organizational skills
- Excellent communication (oral and written) and attention to detail

- Ability to learn new techniques, perform multiple tasks simultaneously, keep accurate records, follow instructions, and comply with company policies
- Experience in managing a stability program.
- Qualified to provide scientific evaluation on projects and studies using a range of analytical techniques and instruments.
- Experience in managing regulatory audits such as the FDA
- Bachelor's degree in relevant field such as chemistry, biochemistry, biology, chemical engineering, pharmaceutical sciences, or other directly related field or degree with comparable coursework in the above areas.
- Familiarity and/or experience in a laboratory setting is preferred
- 2+ years of experience within a Quality Control Laboratory environment in a pharmaceutical industry.

Benefits & Compensation:

This position offers a competitive total compensation package, including health benefits (medical, dental, and vision), 401k with company match, life insurance, and paid vacation and personal time.