Job Description
Stability Coordinator

Job Function Summary

The Stability Coordinator will be responsible for managing the Stability program for the QC/R&D laboratories at Oxford. Execution of the stability program includes initiating stability protocols, stability inventory schedules, stability pulls, ensuring timely testing of products, compiling stability reports, and trending data across the shelf-life of Oxford products. In this role, the candidate will collaborate with other departments and manage multiple projects with a commitment to Safety, Quality, and Customer Service.

Core Responsibilities

- Knowledge of cGMPs, USP, and FDA (21 CFR Parts 210 and 211) regulations related to managing the stability program
- Author stability protocols prior to the initiation of the stability study
- Collaborate with QC, R&D and Regulatory Affairs to identify products, testing criteria and type of stability studies required
- Initiate and track stability sample requests per company procedures
- Receive and document stability samples into the respective inventory schedules
- Create stability pull lists for each month, depending on the type of stability study
- Perform timely pulls of stability samples and track timely completion of all stability projects
- Perform testing of stability samples as needed
- Knowledge of analytical laboratory instrumentation (Analytical Balance, pH meter, HPLC, UPLC, Dissolution testers, KF Titrator)
- Proficient in Empower 3 software, and principles of data integrity
- Review stability data to ensure that testing and documentation is performed according to company procedures
- Compile analytical data into stability reports and trend the data over the shelf-life of the products
- Identify and report any out of trend or out of specification data to laboratory management
- Assist laboratory management with investigations related to stability studies
- Support Regulatory Affairs by providing stability data for submission of regulatory documents

Preferred Skills

- Knowledge and experience in a cGMP environment, preferably solid dose pharmaceuticals
- Experience managing a stability program
- Good understanding of USP/NF
- Strong documentation skills, with great attention to detail
- Critical thinking and troubleshooting skills
- Highly motivated individual, who fosters collaboration and teamwork
- Excellent oral and written communication skills
- Good organization skills with the ability to adapt to changing business priorities
- Proficient in Microsoft office
- Ability to multitask and work under minimal supervision

Education/Experience

- BS in chemistry or related field
- Minimum of 4-6 years' experience in a Pharmaceutical cGMP laboratory