JOB POSTING

Job Title: **SENIOR QA/QC ASSOCIATE**
Department: QA/QC Department
Reports to: QA/QC Manager
Salary Range: DOEE
Date of Posting: February 16, 2017

Position Description: Conduct Material Reviews and Dispositions (MRD); lead Stability Program as well as take on the lead role in investigation and approval of Consumer Complaints report into validated software.

Job Duties:

1. Establishes and standardizes the design, documentation, and implementation of an effective stability management system reflected by satisfactory internal and external quality and regulatory audits, and successfully complete submissions to support all JFI products.
2. Manages the stability program; ensures that the required finished product samples are put on stability testing in accordance with SOP for Stability Testing and Analysis, in coordination with the microbiology and analytical laboratories.
3. Generates, reviews and recommends interim and final stability reports to the QA/QC Supervisor
4. Reviews analytical documents, standard operating procedures (SOPs) and, where necessary, writes and/or revises SOPs that apply to stability, and provide comments, as appropriate, to finalize protocols and reports.
5. Manages change controls related to stability; interfaces with Production, QA/QC, R&D and Regulatory affairs to obtain required information and prepares related domestic and International submissions.
6. Monitors studies for deviations, initiates investigations and provides impact assessments leading to satisfactory management/closure of events.
7. Coordinates with the Technical Support department on non-serious Adverse Events and follows up on the non-SAERs forwarded by Technical Support.
8. Assists in the investigations of out-of-spec test results.
9. Writes and approves SOPs, material reviews and dispositions as well as change controls.
10. Performs other duties as may be assigned by immediate supervisor.

Job Requirement:

- BA/BS in Chemistry/ Pharmaceutical Science/ Food Science or related discipline and over 3 years experience in a QA/QC environment, including over 1 year experience in stability coordination/analysis. MS in Chemistry or related discipline and over 1 years experience in a QA/QC environment and experience in stability coordination is preferred
- Knowledge/ Experience in cGMP and other pertinent regulations
- cGMP and regulatory knowledge of relevant FDA and global stability (ICH) guidelines.
- Excellent analytical and problem-solving skills and written and verbal communication.
- Experience with regulatory inspections would be advantageous
- Ability to work in a fast pace environment and to value the importance of teamwork
- Ability to work independently with minimum supervision is preferred

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.

The employee is frequently required to reach with hands and arms, use hands and fingers to handle controls, computer and mouse; talk and hear. Specific vision abilities required by this job include close vision and the ability to adjust focus. This position regularly requires sitting, standing, walking, reaching, bending, and moving about the production and office facilities. May include moderate travel as directed by the immediate supervisor and the ability to lift up to 25 lbs.

We are an equal opportunity employer.