JOB POSTING

Job Title: **QA/QC ASSOCIATE II**
Department: QA/QC Department
Reports to: QA/QC Manager
Salary Range: (DOEE)
Date of Posting: October 17, 2017

Position Description: The QA/QC Associate II assists in the activities with development, application, and maintenance of quality standards for industrial processes. The QA/QC Associate II is responsible for ensuring that all products are tested, approved and meet the established quality standard according to "The Code of Federal Regulations Title 21- Food and Drugs." This position provides support to the QA/QC, R&D, production department and technical support group.

1. Creates finished products, bulk products and raw material specification sheets in accordance with The Code of Federal Regulations Title 21 – Food and Drugs §111.70.
2. Ensures the use of scientifically valid method for each established specification for which testing is required to determine whether the specification meets §111.320.
3. Reviews subset testing frequency in accordance with 21 CFR 111.
4. Reviews and interprets analytical data from third party testing labs and investigations of out-of-specification test results.
5. Assists with stability protocols and testing requirements necessary to establish product shelf-life.
6. Performs the final release of raw materials to use in production, bulks to use for bottling and finished goods for distribution to sales (Incoming QC) via Atlas Software for internal and external communication.
7. Reviews and coordinates vendor raw material CofA's, product specifications, MSDS, and other product-related information from vendors, as instructed by supervisors.
8. Maintains the QA/QC laboratory invoices, purchase orders, and verifies testing charges for accuracy and for authorized signatures.
9. Assists the department with any tasks related to cGMP implementation and maintenance.
10. Coordinates with the Technical Support Department on the investigation of serious Adverse Event Reports, and other customer complaints.
11. Creates and revises SOP's, approves Material Reviews and Dispositions (MRD's) and change controls, as well as assists with any necessary training and implementation of QC procedures.
12. Performs any other related duties as may be required by the Manager.

JOB REQUIREMENTS:

- BA/BS Degree in Chemistry or related discipline with 2 to 4 years experience in a QA/QC environment or MS in Chemistry or related discipline and over 1 year experience in a QA/QC environment
- Knowledge / Experience in cGMP and other pertinent regulations
- cGMP and regulatory knowledge of relevant FDA and global stability 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**.

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 required to occasionally alternate between sitting and standing positions. The employee is frequently required to reach with hands and arms, use hands and fingers to handle controls, computer and mouse; talk and hear. The employee is occasionally required to walk, stand, stop, and lift as required to file documents or store materials throughout the work day. Specific vision abilities required by this job include close vision and the ability to adjust focus. Proper lifting techniques required. May include lifting up to 25 pounds for files, computer printouts on occasion.

We are an equal opportunity employer.

Schedule: 8:00 a.m. to 5:00 p.m. (may be revised by supervisor depending on needs of department), Monday to Friday

Status: Full Time