INTERNET POSTING

Job Title: Quality Assurance Specialist

City: Parsippany
State: NJ

JOB DESCRIPTION:

1. Review and approve batch records for pharmaceutical dosage forms including tablets, capsules, solutions, tinctures, injectables, powder, and ophthalmics for release to the US market.

2. Perform batch release related activities for NDA, ANDA, and grandfathered products.

3. Review and approve stability data and protocols for annual commitment batches & validation activities, including evaluation for shelf-life extension and Field Alert Reports.

4. Log and process product inquiries, product quality related complaints, and pharmacovigilance activities, which may include reviewing, editing and approving product quality related investigations.

5. Assist in ensuring that all commercial products adhere to the requirements of the Drug Supply Chain Security Act through EPCIS data delivery to the end user utilizing TraceLink. This will require experience with the SOM and ProductTrack modules along with knowledge of the infoexchange, PIE, and PIM modules.

6. Maintain internal quality systems including training and Standard Operation Procedure (SOP) updates.

7. Initiate, approve, and track all Change Controls pertaining to internal activities and with external contracted resources.

8. Create, review, and approve Annual Product Review (APR) reports for NDA, ANDA, and grandfathered products.

9. Assist in the implementation and testing of electronic systems for Quality Management and Inventory Control.

10. Manage quality relationships with contract manufacturers, contract packagers and a contract distribution center

EDUCATION AND EXPERIENCE: Requires a Bachelor's degree in Pharmaceutical Science and 2 years of experience in the job offered or 2 years of experience in the Related Occupation.

RELATED OCCUPATION:

Quality Control/Quality Assurance Associate or any other job title performing the following job duties:

1. Approving assembly batch tickets for tablets, capsules, solutions, tinctures and powder.
2. Performing batch release related activities for different products.
3. Reviewing and approving stability data. Reviewing CoA against Specification.
4. Responsible for filling forms and logs, and maintaining accurate and complete records. Conducting investigation of unexpected issues, product quality related complaints and providing solutions to resolve the findings
5. Writing, revising and updating SOPs for tasks performed in the area of assignment.
6. Maintaining documentation for received Raw Material (RM) in SAP
7. Maintaining professional relationship with internal/external departments, and providing support within and outside the Department.

JOB TIME: Full Time

Qualified candidates should send their resumes to careers2@dexcelpharmausa.com.