Job Posting

Position Title: **Officer – QA, Pharmaceuticals**

No. of Position: **10**

Job overview:

Implement Quality Assurance activities adhering to global quality Directives and HSE guidelines with optimum utilization of resources to ensure consistent good quality of products

Responsibilities:

- Quality Management/Continuous Improvement
- Line Clearance and shop floor compliance
- Implementation of Quality Directives, Management and Control of Documents, such as SOPs, Master Documents, etc.
- Implementation of Complaint Investigation system at site
- Handling of Qualification and validation system, change control system, deviations
- Preparing & review the Annual Product Quality Review
- Review of Batch Reworking/Reprocessing/Reincorporation Documents
- Review of Batch Manufacturing & Packing Records
- Coordination of cGMP Training activity including training of the people
- Ensure Compliance and adherence to company Quality Standards, Local FDA, MHRA regulations, by understanding the requirements, performing the gap analysis to find out the gaps in existing system.
- Preparing a compliance plan for closure of gaps
- Execution of compliance plans
- Review of completion for compliance activity
- Review of the regulatory dossiers, as and when required
- Prepare for and attend to external / regulatory Quality audits
- Validations & Qualifications:
- Preparation and review of Validation Master Plan
- Ensure validated status of all equipment, manufacturing processes, and cleaning processes
- Review of validation plans for facility / utilities / equipment / instrument / process / computer / cleaning
- Review of protocols for qualification and validation of facility/ equipment / product / process
- Review and certification of validation reports after execution of validation of facility /equipment / product / process
- Documentation Control:
    - Preparation of quality system SOPs
    - Controlled distribution and archival of documents & record
    - Control of master documents
    - Issuance of batch records and log books

- Assuring quality of products by :
    - Ensuring SOP compliance
    - Management of Events
    - Controlling the changes made to facility / equipment / product / process and master documents by following change control procedure
    - Investigation of Customer complaints / Recall
    - Review of Batch Manufacturing & Packing Records
    - Ensuring implementation of Corrective actions/Preventive actions proposed in Deviations and Customer complaints
    - Ensuring the effectiveness review of the implemented CAPA
- Preparation of annual product quality review
- cGMP Training:
    - To develop training modules and organize training in GMP
    - Develop and execute the overall training program in coordination with all concerned departments
- Other:
    - Preparation and review of site master file
    - Coordinating with various agencies for making of the technical agreements
    - Implementing the pest control program at Drug products
    - Review of maintenance and calibration program

Requirements & Qualifications:

- Graduate /. Post Graduate in Pharmacy with 1 - 3 years of Experience as an analyst in similar role
- GMP & GLP knowledge
- Good coordination & communication skills.
- Knowledge of GMP and regulatory requirements
- Good interpersonal skills and able to manage conflicts

Terms of employment: Individual contributor role

What makes this position unique?

- This position will provide good exposure to work in GMP/ GLP environment and necessary exposure for vertical growth.

Location information: Ankleshwar