PharmaGend

JOB DESCRIPTION

Position – Assistant Manager / Manager – Quality Control (OPT)

KEY DUTIES AND RESPONSIBILITES:

1. Lead and support QC team for daily QC activities by ensuring timely analysis, documentation, and review of RM/PM/FP/IPC/Stability and Process validation samples as per predefined standards.
2. Write and / or review controlled documentation related to laboratory operations or testing such as SOP's, analytical protocols, analysis reports, forms and validation documents.
3. Ensure compliance with FDA/USP/EP/ICH/ChP regulations and internal controlled procedures in the QC Laboratory.
4. Ensure readiness of QC Laboratory in internal / external audits.
5. Maintain data integrity in Quality Control activities and ensure appropriate traceability.
6. Initiate change control documents.
7. Lead and participate in stability program, method validations, technical transfer, method transfer and validation / qualification activities at the site.
8. Participate in New Product Introduction activities.
9. Lead and participate in laboratory investigations. Document laboratory investigation activities or review and approve laboratory investigation reports.
10. Participate in site corrective action / preventive action (CAPA) program. Ensure timely completion of all commitments made under QMS.
11. Lead and participate in key performance indicators for improving laboratory efficiency, monitoring equipment performance.
12. Lead QC Department training program by imparting training to new staff and comply with Analyst Qualification procedure.
13. Escalate the quality events, trends as appropriate to QC Head.
14. Remain abreast of current regulatory, pharmacopeia and cGMP trends.
15. Serve as subject matter expert on laboratory instrumentation and compliance issues.
16. Lead the QC team, evaluate competencies, assign responsibilities, monitor performance, counsel and provide guidance. Plan & monitor the training and development requirements, motivate staff appropriately to build a committed, motivated & competent team.
17. Participate in personnel decisions (interviewing, hiring, performance appraisals, promotions, termination, staff development, improvement plans) regarding subordinate staff.
18. Maintains a safe laboratory environment by implementing recommendations made by EHS.
19. Initiate CAPEX for equipment purchases.
20. Support in budget preparation for QC Laboratory.
21. Any other activities as and when assigned by the Superior.

JOB REQUIREMENTS:

- EDUCATION: Degree in science or related discipline (e.g. Chemistry, Chemical Engineering).
- EXPERIENCE: Minimum 8 years of quality control experience in pharmaceutical manufacturing industry and minimum 2 years of supervisory experience in managing team.

KNOWLEDGE & SKILLS:

- Possess working knowledge of GMP in the pharmaceutical industry.
- Excellent interpersonal and analytical skills, good verbal, and written communication skills.
- Working knowledge of qualification, calibration, and operation of laboratory equipment such as HPLC, GC, FTIR and Dissolution equipment.
- Working knowledge of method development, validation, verification of analytical method.
- Familiarity of 21 CFR Part 11 requirements.

TO APPLY:

Candidates are encouraged to apply this position via email to Phghr@pharmagend.com with the following information in the resume.

- Work experiences and job responsibilities.
- Current and Expected salary
- Reason for leaving.
- Date of availability
- Education background

We regret that only shortlisted candidates will be contacted.