JOB DETAILS:

Job Title	Quality Control Analyst (Chemistry)
Reports to (Title of Line Manager)	Team Lead Chemistry
Department	Quality
Workstation	Namanve Industrial Park.

JOB OVERVIEW:

The QC analyst is primarily responsible for performing a wide range of quality control tests and analyses on raw materials, bulk samples, validation samples, and finished products while ensuring compliance with Good Manufacturing Practices (GMP) and maintaining the quality and safety of products.

KEY RESPONSIBILITIES

1. **Documentation and Reporting:**
   - Promptly record all test results, observations, and data accurately.
   - Generate analytical reports and documentation to be reviewed and filed in compliance with GLP, relevant regulations and procedures.
2. **Data Integrity:**
   - Adhere to data integrity principles and ensure all electronic records, including raw data and metadata, are accurately recorded, stored securely, and protected against unauthorized changes.

3.Quality Compliance:

- Adhere to Good Laboratory Practices (GLP), and other relevant quality and safety regulations during all aspects of work.
- Assist in internal and external audits, and actively participate in implementing corrective and preventive actions (CAPAs).

4. **Training and Development:**
   - Participate in training sessions to improve knowledge of analytical techniques, compliance requirements, and safety protocols.
   - Share knowledge and best practices with other team members to foster a culture of continuous learning.
   - Assist in developing training materials and conducting training sessions as needed.
5. **Out-of-Specification (OOS) Investigation:**
   - Conduct out-of-specification result investigation, root cause analysis, and deviation management and thereafter determine the potential impact on product quality and recommend appropriate corrective actions.

6. **Analytical Method Verification/ Validation:**
   - Participate in the verification and validation of analytical methods used in the Quality Control laboratory and ensure that these methods are accurate, precise, specific, and robust.
7. **Instrument Qualification:**
   - Execute instrument qualification activities to ensure that laboratory instruments used in quality control testing are fit for their intended purpose and comply with regulatory requirements.
8. **Instrument Maintenance:**
   - Perform routine maintenance, calibration, and troubleshooting of laboratory instruments and equipment.
   - Collaborate with the Engineering team to ensure that all equipment is in good working condition and in compliance with applicable standards.
9. **Sampling:**
   - Implement appropriate sampling plans for raw materials, packaging materials, and finished products and ensure that samples are representative and properly labeled, and that they follow defined storage and handling requirements.
   - Maintain accurate and up-to-date records of sample information.
10. **Analytical and Microbiological Testing:**
    - Conduct comprehensive testing and analysis of raw materials, packaging materials, and finished products following established procedures and specifications.
11. **Stability Testing:**
    - Design and execute stability studies for products according to regulatory guidelines and procedures and stability protocols.
    - Monitor and evaluate product stability over time to ensure that the quality and efficacy of products are maintained throughout their shelf life.
12. **Safety and Compliance Culture:**
    - Promote a culture of safety, quality, and compliance within the manufacturing plant.
13. **Continuous Improvement:**
    - Contribute to the continuous improvement of quality control processes, methodologies, and systems to enhance efficiency, accuracy, and overall quality standards.

Academic Qualifications:
Bachelor's degree in Chemistry, Analytical Chemistry, or a related field.
Job-Related Experience, Skills and Knowledge:
• Minimum of 2-3 years of experience in an analytical chemistry laboratory, preferably within the pharmaceutical or biotechnology industry. • In-depth knowledge of documentation, Sampling, Calibration and maintenance of analytical instruments and equipment, equipment qualification, handling of laboratory standards, reagents and volumetric solutions, reserve samples, method validation/ verification, OOS/OOT investigation and Stability study. • Knowledge of sampling and analysis of packaging materials, water, compressed air and steam is an added advantage. • Proficiency in analytical techniques such as HPLC, GC, UV-Vis, TOC analyser and other relevant methods. Knowledge of GMP regulations and quality control principles. • Strong analytical skills, attention to detail, and proficiency in laboratory software and data analysis tools. • Excellent written and verbal communication skills. • Ability to troubleshoot and resolve analytical and quality issues promptly. • Ability to work effectively in a team environment.

SIGN OFF.

Name of Supervisor: _____

Signature: _____

Date: _____

Name of Job holder: _____

Signature: _____

Date: __