malaysian genomics resource centre

Quality Assurance

RESPONSIBILITIES

1. To liaise with National Pharmaceutical Regulatory Agency or any other regulatory agencies for GMP certification, clinical trial procedures, product registration, etc.
2. Implement all relevant procedures described in the Quality Management System (QMS) and ensure compliance.
3. To review, monitor and approve documents related to Quality Management System.
4. To monitor, review and approve production batch processes, operational activities, standard operating procedures and other quality assurance associated tasks.
5. Ensure that all systems and procedures are effectively in place and periodically revised to meet the needs of current regulatory requirements.
6. To review and approve validation protocols, reports and other relevant documents by ensuring compliances to regulatory requirements.
7. To get involved in all qualification status, instrument calibration records and monitor qualification and calibration schedule of the facility and equipment.
8. To approve and release of finish product batches.
9. Periodically perform internal audit activities to ensure that the existing system in place is being operated in accordance with the established quality and regulatory requirements.
10. Responsible for quality oversight and administration of deviation or investigative programs as well as the establishment of corrective and preventive actions.
11. To review and approve all deviation and out of specification reports, as well as change control documentations.
12. Immediately respond to product complaints and product recall (in case of any product failure) by initiating an investigation and implementing and appropriate countermeasure.
13. Coordinate with auditor, customers or clients visiting cleanroom laboratories.
14. Establish effective relationship with auditors, customers or clients by ensuring product safety and quality compliance matters are addressed appropriately and in timely manner.
15. To approve vendor and supply of raw materials that is intended for GMP manufacturing processes and activities.
16. To eliminate the entry of non-conforming supplier/vendor materials info production area.
17. To ensure that all employees have duly completed their medical examination and approved to perform GMP related activities.
18. To provide continuous GMP training and quality development programs to achieve the highest work competencies.
19. To provide quality assurance direction, support and guidance to internal operational team members ensuring compliances to GMP regulatory requirements.
20. Responsible for the approval of batch release and the verification of QC reports.
21. Perform other duties as assigned.

JOB REQUIREMENTS

1. Candidate must possess at least a Diploma, Advanced/Higher/Graduate Diploma, Bachelor's Degree, Post Graduate Diploma, Professional Degree, Master's Degree, Chemistry, Pharmacy,/Pharmacology, BioTechnology or equivalent.
2. Have experience and knowledge in Document Management System and Risk Management is a must.
3. Well versed in GMP, ISO 9001, 15189 and 17025.
4. Experience in health care industry is an added advantage.
5. At least 3-5 years of working experience in QA field.
6. Required language(s): English
7. Willing to travel to Kota Damansara