B & S GROUP "Believe in us"

JOB DESCRIPTION

ROLE: Sr. Executive / Executive – DQA / QA
SALARY AND BENEFITS: Negotiable
REPORTS TO: Head of Regulatory Special Projects
LOCATION: Vadodara
JOB TIMING: 12:00pm to 09:00pm (IST)

PRIMARY RESPONSIBILITIES:

- To review and authorise analytical test methods, analytical method validation reports, quality control documents and stability testing documents of pharmaceutical formulations, ensuring delivery in accordance with project time scales and deadlines.
- To prepare and review the SOP's, maintenance of BMR (Batch Manufacturing Records).
- To perform internal as well as data audits as needed.

SECONDARY RESPONSIBILITIES:

- Reviews Analytical Development and Quality Control documentation to certify compliance with specifications and procedures.
- Review the analytical methods and specifications for the release of product and raw materials based on Quality Assurance record review and approval.
- Works closely with Operations, Quality Control and Analytical method development to resolve open issues resulting from record reviews of the laboratories, and deviation issues.
- Reviews and approves Corrective and Preventative Actions (CAPA); includes tracking, follow-up, and reporting/trending and evaluating CAPA for effectiveness.
- Interacts professionally with company management, internal departments and other sites to effectively implement and maintain Quality Systems.
- Represents Quality Assurance to guide various project and technical meetings, as needed.
- Works with all departments to guide timely completion of Deviations, CAPA, Change Controls, and Investigations.
- Inputs information from the Quality Systems into electronic databases and generating reports from these systems.
- Captures and reports metrics from Quality Systems.
- Document creation and review, including Standard Operating Procedures, protocols, and reports.
- Performs Internal Audits and Data Audits, as needed.
- Ensures lab compliance – which includes support of implementing procedures that enhance GMP, GLP and safety.
- Performs all responsibilities in accordance with company policies, procedures, federal regulations and safety requirements.

KNOWLEDGE, SKILLS AND EXPERIENCE:

- Master degree in Pharmacy/Science.
- Minimum of 3-5 years in DQA/QA experience preferred.
- Working as Developmental Quality Assurance/Quality Assurance.
- Sound knowledge about pharmaceutical industry systems.
- Sound knowledge of cGMP, GLP, ICH, WHO, MHRA/USFDA.