

JOB DESCRIPTION

1. Internal Quality Control (IQC) activities in bio analytical lab.
2. Verification and identification of raw data including filled forms and chromatograms generated repeats, re-injections and reintegration.
3. Batch review and verification of Batch Review Record.
4. Verification of validation protocol, validation report, method SOP, analytical report and final study report.
5. Verification of daily activities like calibrations, logbook entries, temperature / humidity records.
6. Review Microsoft Excel calculation sheets for calibration standards, quality control samples and for pharmacokinetic analysis.
7. Verification validated excel templates are used for Method Validation calculations and other calibrations.
8. Verification of all daily, monthly, quarterly, half-yearly and yearly calibration and maintenance of laboratory equipment related activities.
9. To assist Head-Bio analytical.
10. Verification of all monthly logbook entries.
11. Verification of daily activities like Deep freeze temperature / humidity records.
12. Assists to General Manager in the smooth running of the bioanalytical activities through efficient project and quality management in conformance to GLP guidelines.
13. Maintenance of bio analytical staff training records.
14. To intimate the bio analytical staff in the absence of group trainings and for the arrangement of appropriate trainings.
15. Responsible for the identification of repeat analysis and ISR samples.