

Title: Asst. manager

Location: Budihal, Nelamangala Bengaluru.

Experience: 7-12 Years.

Salary Range: 13-15 LPA

1. Handling of Deviations/ Incidents, Laboratory incidents, Investigations and CAPA.
2. To involve in laboratory & manufacturing investigation which includes cross functional department investigation.
3. Participate in evaluation and investigation of relevant QMS elements, change controls, incidents, investigations, CAPA, Laboratory investigations, QRA, media fill sterility failures, aseptic area audits, internal quality audit/self-inspection and compliance verification, etc.,) as required.
4. To participate in external audit (not limited to regulatory agency, Customer, Vendor/ Third party) and to support for the audit observations response to the agency.
5. To perform vendor quality audit for materials, contract testing laboratory, service provider, and critical components audits.
6. To identify and establish Corrective and preventive actions for the deviations/incidents.
7. To ensure the effective implementation of CAPA's implemented for the deviations and during internal audits and regulatory audits.
8. To prepare, review and approval of all QMS SOPs.
9. To review and approve the cross functional department SOPs, Specifications, STP and other Quality system documents. (e.g.: Protocols, Reports, QRM, Audit reports, Trends, Rationales, etc.,) for accuracy completeness.
10. Periodically review outstanding QMS elements and provide the data to Carryout management review meeting.to ensure for its resolution.
11. Follow safety instructions during all relevant activities.
12. Carry out any other specific activity as assigned by Head QA/ designee after Appropriate training.