

JOB DESCRIPTION

ROLE: Executive/Sr. Executive - DQA **SALARY AND BENEFITS:** Negotiable **REPORTS TO: Asst.** Manager - DQA

LOCATION: Vadodara

PRIMARY RESPONSIBILITIES:

- Create and Review of technical documents including analytical method development reports, method validation protocols and reports, standard operating procedures in compliance with regulatory requirements.
- Preparation and Approval of Standard Operating Procedures and ensure the preparation, Issuance, Revision/Review and Retrieval of the documents.

SECONDARY RESPONSIBILITIES:

- Preparation and Approval of Standard Operating Procedures.
- Maintain documentation systems and filing of all relevant records, reports and other documentation associated with projects.
- Preparation of Process Validation Protocols and summary reports based on the Analytical results and Batch documents data.
- To co-ordinate the Qualification / Validation of the Equipment, Systems and Process.
- To ensure the issuance of required documents for Drug and Regulatory Affairs.
- To ensure the preparation, Issuance, Revision/Review and Retrieval of the documents
- To maintain laboratories to GMP standards.
- Any other duties as required.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES:

- Essential Masters in Pharmacy or Masters in Science.
- Required experience for Executive 2-4 years and for Sr. Executive 4-6 years.
- Knowledge of Quality Assurance or Analytical Research and Development.
- Knowledge of cGMP/cGLP.
- Experience of working in an QA, AR&D or Regulatory audit compliance environment.
- Good knowledge of Validation Documents Review.
- Ability to work on own initiative and in a team.
- Excellent writing and communication skills are must.
- Ability to adapt to change.