

JOB DESCRIPTION

ROLE: 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 protocols and reports, standard operating procedures in compliance with regulatory requirements.
- Preparation, Review and Approval of Standard Operating Procedures and Qualification (Facility and Equipment) documents.
- To ensure QMS activities on time.

SECONDARY RESPONSIBILITIES:

- 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 and ensure completion of the Qualification / Validation of the Equipment, Systems and Process activity.
- 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.
- 4-6 years of working Experience required in QA, AR&D, IPQA or Regulatory audit compliance environment.
- Knowledge of Quality Assurance or Analytical Research and Development.
- Knowledge of cGMP/cGLP.
- 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.