

JOB DESCRIPTION

ROLE: Team Leader - Pharmacology **SALARY AND BENEFITS:** Negotiable **REPORTS TO:** Manager Pharmacology

LOCATION: Vadodara

PRIMARY RESPONSIBILITIES

> OPERATIONAL EXCELLENCE

• Responsible for all the Module 2,4 & 5 sections of oral solid product submissions:

- Review of clinical and non-clinical overviews for new product dossier submission.
- Prepare and review deficiency response to agency query related to clinical and non-clinical overview.
- Provide scientific literature support for the regulatory submissions as and when required.

• Responsible strategy development:

- To provide scientific advice for the planning on submission to regulatory authority
- To give Proposal for regulatory strategies to file dossier and deficiency.

> STAKE HOLDERS:

- To coordinate with UK team in case of any issues for submission.
- Co-ordination with CMC team for smooth regulatory submissions.

> INNOVATION AND TRAINING:

- Provide training to team members for the preparation of document for the regulatory submission as per regulatory requirements.

SECONDARY RESPONSIBILITIES

- Work on other regulatory related work as and when required.
- To provide scientific literature support to any of the RnD department to resolve issues related to development of product with respect to regulatory strategies.
- Review of Module 1 documents

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES

- Should be Postgraduate in Pharmacy (Pharmacology).
- Good English and Excellent Communication skill.
- Able to work as per UK timing.
- Should have positive attitude towards work and have a team spirit.