

JOB DESCRIPTION

ROLE: Regulatory Executive

SALARY AND BENEFITS: Negotiable **REPORTS TO:** Regulatory Team Leader

LOCATION: Vadodara

PRIMARY RESPONSIBILITIES:

- To find out the references regarding the clinical and non-clinical sections of the dossier.
- Responsible to write the clinical overview and non-clinical overview from the cited references should be involved in filing a dossier for Europe market.
- To compile the CTD Modules as per ICH requirement.
- To evaluate BE studies generated by CRO and utilised it to present in clinical overview.
- Should be involves in communication with other teams during filing process for chasing documents and solving regulatory queries.
- Preparation of module 1 documents.
- Support the stake holders/submission activities by providing necessary information, justifications and reports.

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.

Cab services available for Female candidates (Pickup & Drop).