

JOB DESCRIPTION

ROLE: Regulatory Executive

SALARY AND BENEFITS: Negotiable

REPORTS TO: Regulatory Team Leader

LOCATION: Vadodara

JOB TIMING: 12: 00 P.M. to 9:00 P.M.

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 involve 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

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