JOB DESCRIPTION

ROLE: Regulatory Manager
SALARY AND BENEFITS: Negotiable
REPORTS TO: Pharmaceutical Development Director
LOCATION: Vadodara

PRIMARY RESPONSIBILITIES

You will be involved in the submission and monitoring of successful pharmaceutical licence applications by liaising with various governing boards to obtain granted licences as soon as possible.

SECONDARY RESPONSIBILITIES

- Developing and executing regulatory strategy for new products
- Preparing dossiers accurately for submission to governing boards as well as retaining and organising relevant licence documentation efficiently.
- Reviewing regulatory documents such as manufacturing batch records, packaging batch records, analytical method, validation protocol and reports
- Responsible for compiling regulatory documents including all Modules for submission according to local requirements
- Responsible for coordinating with cross-departmental teams such as Contract Lab and Contract Manufacturer for timely submission if required, collection of documents, review of documents and resolving any regulatory discrepancies
- Keeping up to date with regulatory issues in drug development processes and working to eliminate or minimise regulatory barriers
- Responsible for deficiency reply received from agency
- Maintenance of database with regulatory submission and approval
- Managerial duties:
    - Organising daily objectives/tasks in line with KPI's
    - Conducting one to ones and team meetings regularly
    - Developing the teams' skills to ensure work is carried out as efficiently and accurately as possible
    - Identify skill shortfalls in team members and put in place development plans to address these.
- Provide holiday and absence cover when required, in other roles.
- Ad hoc projects when required
- Any other duties as required.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES

- Previous experience in a similar role is required
- Knowledge of completing a dossier for EU countries through DCP, MRP, National procedures
- Knowledge of completing a dossier in Nees or eCTD submission
- Clear communication skills both written and verbal
- Can demonstrate excellent analytical skills
- Ability to demonstrate openness to change
- High attention to detail
- A conscientious and innovative individual who shows attention to detail.
- Possess good working knowledge of Microsoft Office
- Ability to keep up-to-date with Pharmaceutical trends and developments within the industry.