JOB DESCRIPTION

ROLE: Regulatory Executive

SALARY AND BENEFITS: Negotiable

REPORTS TO: Regulatory Team Leader

LOCATION: Vadodara

PRIMARY RESPONSIBILITIES

- Responsible for compiling regulatory documents including all Modules for EU regulation.
- Reviewing regulatory documents such as manufacturing batch records, packaging batch records, analytical method, validation protocol and reports.
- 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.

SECONDARY RESPONSIBILITIES

- Maintenance of database with regulatory submission and approval.
- Proactively keeping up to date with Regulatory guidance.
- To prepare documents for applications, renewals and variations from start to end.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES

- Good understanding of CMC.
- Knowledge of completing a dossier for EU countries through DCP, MRP, National procedures Good knowledge of life cycle management of products.
- Knowledge of completing a dossier in Nees or eCTD submission.
- Clear communication skills both written and verbal.