B & S GROUP "Believe in us"

JOB DESCRIPTION

ROLE: Sr. Executive – Regulatory Affairs(CMC)
SALARY AND BENEFITS: Negotiable
REPORTS TO: Assistant Manager/Team Leader - Regulatory Affairs(CMC)
LOCATION: Baroda, India

PRIMARY RESPONSIBILITIES:

- To review the Module 3 documents as per eCTD requirements.
- Review of RSD, Q1/Q2 documents, GMP documents, R&D documents, PDR, AMV and other regulatory documents.
- To verify the submission package for the eCTD processing.
- To ensure timely submissions of initial MAA and any other procedures.
- Working closely with all the stake holders for smooth regulatory submissions.
- Tracking of all documents required for regulatory submissions.
- Preparation/maintenance of databases related to regulatory submissions.
- Preparation of effectiveness charts, monthly reports and weekly reports.

SECONDARY RESPONSIBILITIES:

- Preparation of dossier sections and responses as per the deficiencies received from agency.
- Follow-up with cross-functional teams for the timely availability of the required documents.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES:

- Master in Pharmacy with minimum 2 years of work experience.
- Excellent computer skills, including adobe acrobat software, MS word and MS excel.
- Sound technical knowledge in the field of eCTD guidances and processing.
- Well-versed with any of the eCTD tools.
- Work independently with minimum supervision.
- Good communication and presentation skills.