B & S GROUP "Believe in us"

JOB DESCRIPTION

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

PRIMARY RESPONSIBILITIES:

- Responsible for regulatory submission of different dosage forms.
- Co-ordination with all the stake holders for smooth regulatory submissions.
- Review and finalization of regulatory strategy document and Module 3 documents as per eCTD requirements.
- Review of internal assessment reports and comparison with Agency's assessment report.
- Actively participating in project meetings, regulatory meetings and other important meetings.
- Preparation/review of effectiveness charts, monthly reports and weekly reports.
- Review of Q1/Q2 documents, GMP documents, R&D documents, PDR, AMV and other regulatory documents.
- Maintenance of database related to regulatory submissions.

SECONDARY RESPONSIBILITIES:

- Review of dossier sections and responses as per the deficiencies received from agency.
- Co-ordination with all the RA colleagues for smooth submissions.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES:

- Master in Pharmacy with minimum 4 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.