B & S GROUP "Believe in us"

JOB DESCRIPTION

ROLE: Executive / Sr. Executive – Regulatory Affairs
SALARY AND BENEFITS: Negotiable
REPORTS TO: Head of Regulatory Affairs
LOCATION: Baroda, India

PRIMARY RESPONSIBILITIES

- To prepare and upload the dossier sections in the eCTD software.
- To compile, verify and hyperlink submission package for the eCTD processing.
- To ensure timely submissions of initial MAA, variations and any other procedures.
- Working closely with other regulatory teams to ensure proper and correct processing of the files for eCTD processing.
- Maintenance of submitted applications database throughout the life-cycle of the products.
- To prepare product approval packages for the approved products.

SECONDARY RESPONSIBILITIES

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

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES

- Master in Pharmacy with 2-5 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.