B & S GROUP
"Believe in us"

JOB DESCRIPTION

ROLE: Regulatory compliance officer
SALARY AND BENEFITS: Negotiable
REPORTS TO: Assistant Regulatory Manager
LOCATION: Vadodara
JOB TIMINGS: 11:00am to 08:00pm (India time)

PRIMARY RESPONSIBILITIES

- Provides reports on a regular basis, and as directed or requested, to keep the management informed of the operation and progress of compliance efforts.
- Implementation of all necessary actions to ensure achievement of the objectives of an effective compliance.
- Identification and prioritization of compliance issues, as well as development and implementation of compliance plans. May also be required to complete and submit regulatory agency applications and reports.
- Identifies potential areas of compliance vulnerability and risk; develops/implements corrective action plans for resolution of problematic issues, and provides general guidance on how to avoid or deal with similar situations in the future.
- Work closely with relevant regulatory and quality functions (MHRA/HPRA/EMA) to coordinate the compilation of regulatory submission components to support variations, renewals and ensure submissions are made on time and in accordance with relevant procedures.
- Provides regulatory advice and guidance to change controls and deviations and determines the regulatory impact. Raise regulatory change controls and manage relevant systems and databases to ensure proposed regulatory changes are tracked and approvals communicated effectively to relevant quality functions (QPs, QA & materials management) in a timely manner.

SECONDARY RESPONSIBILITIES

- Handling Parallel imports licencing work for MHRA, IMB and EMA that includes preparing documents for applications, renewals and variations.
- Responding to the queries received from the regulatory bodies (MHRA, IMB and EMA).
- Performing monthly In-house tasks for licence updation and audit for all the three regulatory bodies.
- Maintenance of data bases for the record of activities and tasks completed along with the updation and maintenance of BAR on PI system.
- Generation, follow up and timely closure of change controls necessary for applying for a licence, variation or cancellation.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES

- Excellent oral and written English communication.
- Excellent handling and usage of MS Excel and data analytical skills.
- Attention for details and proactive attitude.
- Good working knowledge of MS Office especially MS word and Excel.
- Sound knowledge on pharmacological front will be an added advantage.
- Good grasping power with ability to learn from mistakes.
- Capability to take initiatives and work as a team.
- Ability to meet tight timelines and product good quality work.
- Preferred BBA/MBA/ degree in healthcare administration.