B & S GROUP "Believe in us"

JOB DESCRIPTION

ROLE: Deputy Process Leader (PLPI)
REPORTS TO: Head of Regulatory Affairs - India
LOCATION: Baroda, India
JOB TIMING: R&D India time

PRIMARY RESPONSIBILITIES

- Handling Parallel imports licensing work for MHRA, IMB and EMA that include reviewing documents for applications, renewals and variations.
- Reviewing query responses for the regulatory bodies (MHRA, IMB and EMA).
- Ensuring monthly In-house tasks for licence updating, renewals and audit for all the three regulatory bodies are completed on time and the work logs are up to date.
- Ensuring the data bases for the record of activities and tasks completed along with the updating and maintenance of BAR on PI system is done and maintained properly.
- Updating the final product links on the Bar after checking of the PILs, labels for product labelling after application/ variation is granted.
- Generation, follow up and timely closure of change controls necessary for applying for a licence, variation or cancellation.
- Interaction with the Commercial department and third party for the licences to be labelled/ bought on monthly basis in response to the orders sent out by them and ensuring the response is given within 24 hours of receiving notification.
- Preparation, updating and maintenance of SOPs for the regulatory processes on timely basis.
- Providing training to the new recruits and guide them through to understand the procedure well.
- Team meetings to identify gaps, doubt clarifications, discussions to strengthen the team.

SECONDARY RESPONSIBILITIES

- Implementing new ideas and suggestions to make the processes simpler and efficient.
- Liaising with the HR, Admin, IT, Regulatory departments for any queries, suggestions and requirements.
- Ensuring the tasks are performed in accordance with the approved SOPs.
- Sending KPI sheets for analysis and analysing the results on weekly basis.
- Identify the Gap points in efficient department functioning and getting it solved for better staff productivity.
- Ensuring office decorum is maintained within the office premises and staff is punctual in reporting to the office.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES

- Excellent oral and written English communication.
- Sound knowledge on pharmacological front.
- Thorough understanding of the application, variation and renewal processes for all the 3 regulatory bodies and being updated about the latest developments in the regulatory requirements.
- Team player with ability to motivate and the bond the team as a single unit and ensure team members are groomed to perform the roles efficiently.
- Proactive attitude and good grasping power.
- Decision making ability with rational approach.
- Problem solving ability and ability to get tasks done on time even under tight deadlines.
- Open to handling new responsibilities with full attention for details.
- Prioritizing the tasks as per the requirement.
- Good working knowledge of MS Office especially MS word and Excel.
- Capability to take initiatives and work as a team.
- Ability to meet tight timelines and product good quality work.