ROW Market – JD (Oral & Parenteral Dosage Formulations)

Designation: Manager/Sr. Manager
Department: Regulatory affairs (Formulations), **ROW**
Experience: 11 to 14 years.
Qualification: M. Pharmacy
Number of Positions: 01

- This position is responsible for ROW Market dossier preparation handling and guide/assist in in team as well as technical review and finalization of documents required for regulatory filing in all respective regions.
- The position should aim at ensuring accurate and high quality documentation on timely basis to meet organizational requirements and to ensure faster approval with minimal queries.
- The position would be responsible for ensuring Regulatory Compliance by keeping the dossier up- to-date throughout the product life-cycle.

Key Accountabilities

1. Competent with ROW-filing requirements with respect to all Modules/requirements (Oral and Parenteral Dosage forms). Ability to independently and effectively review technical documents related to Quality Module.
2. Well versed with ROW Regulatory Guidance and Processes (i.e. Ability to understand and interpret technical expectations as per applicable ICH/respective guidelines)
3. Sound knowledge of basic aspects of Oral and Parenteral Dosage Formulation.
4. Should be aware of Post-approval variation requirements in ROW and have ability to take decisions related to the variation categorization and submission.
5. Should have QA knowledge to enable correct review of related change controls and decide on any impact on regulatory front in terms of variation.
6. Should have excellent work-management, Team Management and time-management skills. Should have flexibility to handle multiple tasks at a time and ability to plan and execute assignments in case of changing organizational priorities.
7. Having positive attitude towards work as well as people.
8. Should be transparent in dealing with the team members and should be able to guide them to bring the best out of them
9. Good interpersonal skills to deal with various cross-functional teams.