Job description for Sr. Officer / Executive - RA

Apply Online at https://lnkd.in/gvT-zhc2

Job position	Sr. Officer / Executive
Educational qualification	Graduation/post-graduation in Pharma, science or any life science
Function/department	Regulatory affairs
Expected year of experience	4+ years

Mandatory technical skill and experience

1. At least 4 years of experience in Regulatory Affairs
2. Hands on dossier handling (M1 to M5) in Europe & Australia region for OSD
3. Dossier preparation in other regions like, US, South Africa, GCC and ROW is considered as add on experience
4. e-CTD software management

Other skills

1. Good verbal and written communication skills
2. Should be a team player
3. Must be able to meet deadline with a positive attitude and atmosphere

Key Responsibilities

1. Coordinate with the cross functional team members for the documents
2. Hands on review of technical documents like specifications, AMV, CDP, stability reports
3. Prepare and review product labels for Europe and other markets
4. Preparation and compilation of IND dossier for submission to EU, TGA and semi regulated market.
5. Preparation of variation sequence
6. Respond to the queries within assigned timelines.
7. Maintain regulatory database and documentation.
8. Develop and manage regulatory tracking systems to monitor submission timelines and approvals.

The link to apply and upload your CV - https://forms.gle/XvsZvXmPbUxGYydg6