

Job Description - Plant RA	
<b>Experience required</b> – 4 to 7 years	
<b>Number of Persons Required</b> – 01	
<b>Function</b> – Regulatory Affairs	
<b>Position:</b> Plant RA – Sr.Executive / Asst. Manager	
<b>Location:</b> JEPL Manufacturing Site, Karkapatla.	
<ul style="list-style-type: none"> <li>➤ This position is responsible for Technical Review Plant documents and finalization and guide/assist with CFT's for finalization of Plant documents and sharing the final approved documents for regulatory filing (Russia/ROW/EU).</li> <li>➤ The position should aim at ensuring accurate and high quality documentation review and approval on timely basis to meet organizational requirements and to ensure quick support for dossier preparation.</li> <li>➤ The position would be responsible for ensuring Regulatory Compliance &amp; documentation sharing/maintaining by keeping the respective country dossier requirements.</li> </ul>	
<b># Key Accountabilities</b>	
<b>Process/ Operational:</b>	
1	Ability to independently and effectively review technical documents related to R&D and QA/QC data (ex. BMR/BPR/PDR/PVR/Specifications...etc...).
2	Sound knowledge of basic aspects of a OSD & Parenteral Dosage Formulation requirements
3	Should have basic QA knowledge to enable correct review of related change controls and decide on any impact on regulatory front in terms of variation.
4	Should have basic knowledge in dossier filing requirements with respect Quality documents for OSD & Parenteral Dosage forms.
5	Well versed with Regulatory Guidance and Processes (i.e. Ability to understand and interpret technical expectations as per applicable ICH and country guidelines)
6	Should coordinate with all CFT's in order to get approved R&D/Plant documents in time and maintain the status of ongoing and upcoming projects status for different markets.
7	Able to coordinate with CFT's and resolve the queries related to regulatory approach
8	Over all responsible for plant documentation review and approval w.r.t. Regulatory Affairs
<b>Strategic:</b>	
1	Should have excellent work-management and time-management skills.
2	Should have flexibility to handle multiple tasks at a time and ability to plan and execute assignments in case of changing organizational priorities.
<b>People Related:</b>	
1.	Having positive attitude towards work as well as people.
2.	Should be transparent in dealing with the team members and should be able to guide them to bring the best out of them
3.	Good interpersonal skills to deal with various cross-functional teams.
<b>Role Holder Profile</b>	
<b>Education</b>	B. Pharmacy/M. Pharmacy
<b>Basic Skills</b>	Good written and verbal drafting and communication skills, Sound Computer knowledge of basic software (e.g. MS-office).