EU Market – JD (Parenteral Dosage Formulations)

Experience required – 4 to 7 years.

Number of Persons Required – 01

Job title	Sr. Executive or Asst. Manager
Function	Quality Module, Regulatory affairs (Formulations), **Europe Market**
Reports to	Head - Regulatory Affairs (Formulations)

This position is responsible for EU dossier preparation and guide/assist in technical review and finalization of documents required for regulatory filing in EU.

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**
Process/ Operational:	
1	Competent with EU-filing requirements with respect to Modules 2 & 3 (Parenteral Dosage forms). Ability to independently and effectively review technical documents related to Quality Module.
2	Well versed with EU-Regulatory Guidance and Processes (i.e. Ability to understand and interpret technical expectations as per applicable ICH and EMEA guidelines)
3	Sound knowledge of basic aspects of a Parenteral Dosage Formulation (primarily pharmaceutical development along with general analytical aspects)
4	Should be aware of Post-approval variation requirements in EU and have ability to take decisions related to the variation categorization. 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.
Strategic:	
1	Should have excellent work-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.
People Related:	
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.

Role Holder Profile

Education	M. Pharmacy
Experience	4 – 7 years *(preferably with sufficient hands on experience in Europe Regulatory Affairs).*
Basic Skills	Good written and verbal drafting and communication skills, Sound Computer knowledge of basic software's (e.g. PDF, MS-office/Excel).