translumina
LIMITLESS POSSIBILITIES

Job Description	
Designation	Head – Regulatory Affairs
Experience	10-15 years of relevant experience
Reports to	Director - Manufacturing
Location	Dehradun

Job Purpose

Strategize registration and post registration activities for all products in the specific region to facilitate achievement of business priorities and ensure compliance. Track and Monitor Regulatory Assurance & Training. Overall management of RA Data system. Oversee activities of Licensing Team.

Major Requisition

- Extensive knowledge of EUMDR and applicable government regulations.
- Understanding of Technical master files and ability to make necessary modifications as per EUMDR.
- Experience with Class III medical devices in Vascular Intervention will be an added advantage.
- Ability to inform and educate managers and department heads on regulations as well as polices that require compliance.
- Knowledge of Drug pharmacology, kinetics, release, stability studies, microbiology etc.
- Knowledge of regulations pertaining to DCGI.

Requisite Skills

- Communication Skills (clarity of thought, comprehension)
- Likely potential for growth
- Job / Product / Technical Knowledge / Pharma domain knowledge
- Presentation & Interpersonal skills (If applicable)
- Managerial or People Management skills
- Safety awareness (If applicable)
- Relevance of Previous Experience
- Comprehension, Analytical & Problem solving abilities
- Productivity & Result Orientation (If applicable)
- Attitude
- Qualification fitment
- Personality traits (Individualistic / Team player, Out spoken, Maturity level etc.)