Position: Director, Regulatory Affairs - Generics
Location: Princeton, NJ

Sun Pharmaceutical Industries Inc. (Sun Pharma) is the fourth largest specialty generic pharmaceutical company in the world with global revenues of over $ 4.5 billion US Dollars. Supported by more than 40 manufacturing facilities, we provide high-quality, affordable medicines, trusted by healthcare professionals and patients, to more than 100 countries across the globe including the United States. Sunology is a combination of Sun Values and Ideology and is the way of life at Sun Pharma. Sunology is Humility. Integrity. Passion. Innovation. It represents our promise to all stakeholders including patients, physicians, and employees. **This position is located in Princeton, New Jersey. The work week is HYBRID: 3 days in office; 2 days remote.**

Job Summary:

The Director, Regulatory Affairs - Generics shall be responsible for providing leadership to regulatory function for US. The incumbent will be designated as US agent for all generic application. The job will include engagement with US FDA on various matters including new submissions, existing product lifecycle management, supply of products in the US, and other matters, management of team at Princeton office, and regulatory support to US based manufacturing.

Area of Responsibility:

- Serve as principal regulatory contact for all interactions with US FDA. Ensure timely dissemination of information to stakeholder. Work closely with corporate RA teams to get the required feedback from FDA.
- Provide strategic, tactical, and operational direction and guidance for Sun Pharma products pipeline and key regulatory milestones.
- Lead US regulatory activities for the set of projects handled by US regulatory team.
- Provide regulatory inputs to business development in terms of product approval.
- Ensure due diligence for new proposals.
- Responsible for developing, executing, and maintaining the regulatory commitments and requirements for assigned programs.
- Ensure evaluation of regulations, directives, guidelines and policies, etc. that could potentially impact on product development till approval and lifecycle management post approval.
- Actively engage with FDA.

Education and Qualifications:

Post-graduation in Pharmacy or Science, PhD will be preferable.
Specialization in project management/general management will be added qualification.

Experience:

Should have 15 or more years of experience in a similar capacity; Generics experience required.

Benefits Offering:
Medical, Dental, Vision Benefits
Health Savings Account (HSA), Flexible Spending Account (FSA)
Prescription Drug Coverage
Telehealth and Behavior Health Services
Income Protection – Short Term and Long-Term Disability Benefits
Retirement Benefits - 401k Company Match on Day One (100% vesting immediately)
Group Life Insurance
Wellness Programs
Corporate Discounts on personal services: Cellular phones, Entertainment, and Consumer Goods