REGULATORY AFFAIRS MANAGER

Position Summary

This position will provide regulatory and technical expertise into the company's development plans of its product candidates. The Manager will work closely with the Regulatory Affairs department to plan and coordinate all regulatory submissions and activities from pre-submission to approval of assigned projects/applications. He/she will be responsible for providing operational leadership, for assessing regulatory authorities' data requirements, for authoring certain portions, and for overseeing editing and publishing of final submissions to meet appropriate requirements. He/she will develop and maintain excellence in knowledge of worldwide regulatory procedures and requirements.

Essential Job Functions

- Work within the Regulatory Affairs Team in conjunction with the Research and Development Team to fully prepare and file submissions to the FDA for new products, amendments and supplements in eCTD format to achieve one cycle approvals.
- Serve as a regulatory subject matter expert to guide teams on regulatory related issues by communicating effectively with the appropriate departments.
- Plan and coordinate the timely preparation and publishing of all US Regulatory submissions for designated projects and ensures technical accuracy and regulatory compliance of all submissions (e.g. INDs, NDAs and ANDAs).
- Provide operational regulatory input and guidance in cross-functional teams. Work flexibly within and across functional areas to provide broad regulatory support to ensure the delivery of product team and business objectives. Contributes to solutions to regulatory issues.
- Responsible for ensuring planned drug development activities comply with regulations/guidelines and providing a critical analysis of the risks and issues.
- Work collaboratively within the Regulatory team for seamless transition of products from research and development to commercialization.
- Serve as a member of cross functional new product development teams by assessing regulatory requirements needed to achieve rapid market approval.
- Interacts with regulatory agency personnel in order to expedite approval of pending applications and to resolve regulatory matters.
- Manage, coach and develop junior RA staff members in a constructive, transparent manner.
- Actively contribute to the creation and sustaining of a viable career path within the department.

Qualification/Skills

- Minimum B.S. degree in a scientific discipline.
- 5+ years regulatory experience in pharmaceutical industry.
- Must have direct hands on experience preparing and filing IND, NDA and ANDA submissions, annual reports, sNDA, etc. in eCTD format.
- Prove ability to interpret regulations, to define and communicate regulatory strategy to teams across multiple programs as well as experience running FDA meetings.

- Thorough knowledge of the ANDA drug development process.
- Understanding of scientific methods and the ability to interpret and communicate scientific data to the Regulator Authorities.
- Strong Working knowledge of US FDA regulatory requirements, C F R , GFI and ICH.
- Excellent project management and organization skills.
- Excellent communications skills (verbal and written) and interpersonal skills.