

INTERNET POSTING

Job Title: Sr. Regulatory Affairs Manager
City: Parsippany
State: NJ

JOB DESCRIPTION:

- Directly supervise and train junior Regulatory Affairs professionals, provide mentorship and strategic direction to ensure regulatory objectives align with business goals.
- Coordinate prepare and review all assigned regulatory submissions , including ANDAs and 505(b)(2) NDAs, ensuring adherence to submission timelines and FDA guidelines.
- Develop and implement increasingly complex and technical regulatory strategies throughout assigned product's lifecycle, from development through post-approval, ensuring timely approvals.
- Proactively address challenges and assist in ensuring the company's compliance with all applicable regulations.
- Ensure regulatory project timelines for assigned projects are aligned across teams, secure successful filings and approvals.
- Author and review departmental SOPs, ensure compliance with regulatory requirements and optimize submission processes.
- Coordinate and manage regulatory strategies for product lifecycle management.
- Monitor regulatory and cross-functional timelines for assigned projects to ensure alignment for successful regulatory filing and approvals.
- Manage regulatory risks, ensure all regulatory documents are accurate, complete, and compliant.
- Change control assessment for post approval changes to approved ANDA and NDA.
- Act as a regulatory technical expert between the firm and FDA for assigned ANDAs of drug products. Effectively communicate and interact with Regulatory Project Managers and Regulatory Business Project Managers (RPMs and RBPMs) at FDA.
- Manage GDUFA Self-Identification, Program Fee Assessment, CARES ACT Reporting, Controlled Correspondence filings and applicable regulatory filing

information including, annual establishment registration renewals, etc.

- Review draft guidances issued by US FDA and contribute to technical and regulatory discussions leading towards the preparation and submission of company comments to FDA.
- Develop and maintain a deficiency tracker database to help increase consistent regulatory approaches across projects and decrease reoccurrence of deficiency comments from the Agency.

EDUCATION AND EXPERIENCE REQUIREMENT: Requires a Master's degree in Epidemiology and 3 years of experience in job offered or 3 years of experience in the Related Occupation.

RELATED OCCUPATION:

Sr. Regulatory Affairs Associate or any other job title performing the following job duties:

- Coordinate prepare and review all assigned regulatory submissions , including ANDAs and 505(b)(2) NDAs, ensuring adherence to submission timelines and FDA guidelines.
- Proactively address challenges and assist in ensuring the company's compliance with all applicable regulations.
- Ensure regulatory project timelines for assigned projects are aligned across teams, secure successful filings and approvals.
- Author and review departmental SOPs, ensure compliance with regulatory requirements and optimize submission processes.
- Manage regulatory risks, ensure all regulatory documents are accurate, complete, and compliant.
- Change control assessment for post approval changes to approved ANDA and NDA.
- Review draft guidances issued by US FDA and contribute to technical and regulatory discussions leading towards the preparation and submission of company comments to FDA.

SALARY RANGE: \$179,296.00 to \$185,000.00/year

JOB TIME: Full Time