https://www.biolink360.com/job/regulatory-affairs-associate-director-nj-2/

Regulatory Affairs Associate Director-Pharma

Hiring organization
BioLink 360

Employment Type
Full-time

Job Location
Newark, NJ
Remote work possible

Date posted
March 8, 2023

Description

Title: Associate Director of Regulatory Affairs -Ad Promo

Reports to: EVP Regulatory Affairs

Direct Reports: 1

Location: Northern NJ-Morris County

Salary Range: 150-190K

Work Location: Hybrid

Experience Needed: Solid foundation in ad/promo regulatory affairs, with a total of 7 years in Pharma Regulatory. This is a working Manager position, and as the team grows, leadership responsibilities will expand.

Our client is a global pharma company that has over 40 years of experience, with over 300 products and close to 4000 employees. The person hired for this role will have a concentration in the women's health portfolio. This is an established company based in Northern New Jersey, with a recent FDA approval which will largely be the initial focus of this role. The person hired will set strategy and execute the plan with a collaborative and passionate team.

Responsibilities

- Responsible for preparing and submitting NDA annual reports, supplements, and other submissions required for marketed drug products in eCTD format.
- Provide regulatory assessment of CMC change controls. For changes requiring the filing of supplemental NDAs, prepare and submit relevant documents and updates to the dossiers for approval.
- As a member of the Promotional Review Committee, ensure the review and approval of branded and unbranded promotional materials are in regulatory compliance with relevant laws and regulations.
- Lead the implementation of labeling changes for drugs, medical devices and dietary supplements including tracking and maintaining NDC/NHRCI numbers and labeling component and versions numbers.
- Ensure regulatory compliance of marketed dietary supplements in terms of labeled claims and promotional materials.
- Maintain and update establishment registrations and drug listings.
- Maintain and update regulatory SOPs and support the review and implementation of policies and procedures.
- Represent the company in NJ State and FDA site inspections.
- Act as the designated representative for company's manufacturer and wholesale distributor licenses.

Qualifications

- Bachelor’s degree in Chemistry or equivalent
- Fluent in English. Proficiency in Spanish is desirable.
- +7 years of experience in regulatory affairs.

Key Words:

Regulatory Advertising & Promotion Policy, Adpromo, Ad Promo, Regulatory Affairs, RAC, PharmD, Scientist, Technical Writer, Labeling, RA, Reg