



NDA/ANDA Regulatory Affairs Project Manager

Location: Allegan, Michigan

About Perrigo

Perrigo Company is a leading global healthcare supplier that develops, manufactures and distributes over-the-counter (OTC) and prescription pharmaceuticals (Rx), nutritional products, active pharmaceutical ingredients (API) and consumer products. Perrigo Company is the world's largest manufacturer of OTC pharmaceutical products for the store brand market with over \$2 billion in annual sales. The Company's primary markets and locations of manufacturing facilities are the United States, Israel, Mexico and the United Kingdom.

Perrigo produces more than 44 billion tablets annually, is the largest producer of liquid antacid and the second largest producer of acetaminophen and ibuprofen. Perrigo has more OTC ANDA approvals (61) than any other company (including branded companies).

Job Description

The ANDAs/NDAs submissions group in Regulatory Affairs has an immediate opening for a Regulatory Affairs Project Manager for ANDAs/NDAs. The ANDAs/NDAs submissions team is responsible for working with many groups in the Company and with FDA for the filing and approval of Perrigo's new drug applications. Responsibilities include (but are not limited to):

- Assemble and review data and information required for new drug application submissions and amendments. Includes CMC, Bioequivalence, and Labeling Section for OTC and Rx applications for ANDAs and 505(b)(2) NDAs.
- Work closely with all relevant departments to ensure availability of proper documents for timely filing of approvable submissions.
- Effectively communicate with FDA personnel in order to resolve issues and ensure expeditious approvals.
- Participate in formulation of submissions and approval strategies for projects in the department.
- Communicate with consultants, attorneys, and customers as needed to ensure proper understanding of product status and relevant FDA requirements.
- Assemble and file supplements to approved ANDAs and NDAs.
- Ensure compliance in post-approval activities including manufacturing, controls, labeling, and trade dress evaluations.
- Lead or participate in various task force activities related to new applications and supplements.

Qualifications

B.S. in a scientific or technical field with five plus years increasing responsibility in Regulatory Affairs required. Ten plus years in an FDA regulated industry highly preferred. Experience with the filing of ANDAs and/or NDAs highly preferred. Strong interpersonal skills and ability to effectively interact with FDA and company personnel at all levels required. Excellent technical writing and strong verbal communication skills are required.

Qualified applicants are requested to apply online at www.perrigo.jobs, under 'US Careers.'

Perrigo Company is an Equal Opportunity Employer.

Perrigo Company
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