Director of Regulatory Compliance

As our Director you will be responsible for all activities of the Regulatory Affairs Department.

Your main objective is to ensure our regulatory compliance - specifically with FDA, OSHA, DOT, EPA, and all federal, state, and local regulatory authorities. If you're tired of bureaucratic decision-making, join our small, privately-owned, financially strong team. You'll be making a significant impact in our company as a key contributor.

Key Responsibilities

- Lead the FDA inspectors during inspections. Answer their questions and negotiate with FDA on all issues.
- Coordinate and process documents for registrations and periodic submissions.
- Review and submit Annual Reports, Periodic Reports, Annual Drug Reviews, Adverse Drug Experiences and Recall Coordination Activities, and supplements to FDA.
- Direct Quality and Regulatory Management meetings, evaluate project priorities and coordinate activities to facilitate the reaching of objectives in a timely manner.
- Direct and develop staff within the QC/QA, R&D, Marketing and Manufacturing departments. Lead data generation and strategy development. Interpret regulations and provide consultancy for company’s compliance needs.
- Develop and maintain regulatory knowledge by keeping abreast of regulatory, pharmacopeia and cGMP changes.
- Act as subject matter expert for our drug, medical device, and food products, when customer inquiries occur.
- Write, review and revise SOP’s, in compliance with the regulations.
- Review and approve protocol changes. (Lab, Manufacturing, Packaging Masters, etc).
- Maintain established Quality Systems with respect to Investigations, Change Controls and Corrective and Preventive Actions.
- Provide regulatory/technical input for product development and reformulation.
- Direct or perform cGMP training and internal audits.
- Review and approve drug advertisements / promotion materials, in compliance with current regulations.
- Manage change control system for drug, medical device, and food products.
- Investigate and respond to OOS, deviation, complaint and other deficiencies.
- Perform other activities as necessary.
Qualifications

- BS/BA in Biochemistry, Biology, or Pharmaceutical Sciences is a minimum. Pharm D. or advanced degree in a scientific/technical discipline is preferred.
- Five to seven years of pharmaceutical industry experience and a minimum of three years direct experience with FDA. Candidate must show strong negotiation skills and significant experience in interacting with regulatory authorities.
- Must have previous experience in pharmaceutical or medical device industries.
- Must have previous experience in supervising / managing staff. Must also have ability to work on long-term projects independently.
- Must have excellent communication skills- verbal, written, and interpersonal.
- Must have strong analytical, strategic, organizational, reporting and presentation skills.
- Must have a working knowledge of word processing, database, and spreadsheet applications.
- Must have the ability to multitask and exercise good judgment.

Company hours are typically Monday – Friday 8:30 – 5:00. Your schedule could vary somewhat, dependent on your needs, and subject to negotiation. We also offer a casual work environment.

Job Type: Full-time

Job Location: Fishers, IN

Required education: Bachelor's

Required experience: Regulatory Compliance: 5 years