

SePRO CORPORATION**JOB DESCRIPTION**

Job Title: Regulatory Affairs Manager
Department Name: Research and Regulatory Affairs
Location: Carmel, IN
Supervisor(s) Title: Vice President, Sales and Research

JOB SUMMARY

Under the direction and periodic review of the Vice President, Sales and Research, the Regulatory Affairs Manager is responsible for the creation and execution of regulatory functions and strategies to obtain, support, defend, and maintain the international, federal, and state registrations of SePRO products in the aquatic, turf and ornamental, and agricultural markets.

PRIMARY RESPONSIBILITIES

1. Manage SePRO's federal registrations with US EPA for new and existing products. In this process, it is important to work with appropriate personnel, including the Vice President, Sales and Research, to develop and implement the regulatory strategy. This involves completing the necessary submissions and interfacing with regulatory contacts, working with business unit personnel and researchers to develop product labels, and managing regulatory studies to meet data requirements. When required, manage regulatory strategy with the assistance of external regulatory consultants.
2. Lead and mentor the Regulatory Affairs Specialists and other personnel assigned. This includes delegating and assigning work to Specialists, setting their action items, yearly goals and reviews.
3. Maintain existing international registrations and interface with international business partners or regulatory consultants as required. Assist in evaluating potential for additional worldwide registrations by working with business partners and other regulatory consultants.
4. Oversee the state registration process for SePRO products to maintain existing registrations and obtain new state registrations. This includes working with the States Registration Specialist in completing the necessary submissions and communicating with state regulatory contacts and outside business partners.
5. Serve as technical expert on regulatory issues with the business units (BUs) to address regulatory concerns to support sales of existing products. This includes frequent interactions with the BUs to ensure business goals are current, achievable and pursued, updates on federal/state registrations, managing information on competitive and potential data compensation issues, and working with regulatory agencies to support product registrations.
6. Manage labeling of products to ensure compliance with EPA and state requirements. Work with the Supply Chain and Communications teams to that ensure package, specimen, and website labels are consistent with the EPA approved label; and that the 'right' label is printed in the 'right' amount to maximize efficiency.
7. Manage Safety Data Sheets (SDS) of products by ensuring compliance with OSHA, GHS and Industry formatting/practice through periodic reviews, and maintain archive file of SDS. Assist the Supply Chain and Manufacturing team to ensure SDS are current.
8. Responsible for the Document Control Center and FIFRA 6(a)(2) reporting. Responsibilities would include filing of regulatory correspondence, documents (state, federal and international), and maintenance of the document database. For 6(a)(2)

- reporting, conduct annual employee training, compile information from personnel on potential adverse effects, and submit documentation to EPA and appropriate states.
9. As required, prepares annual regulatory budgets and timelines, and monitors progress throughout the year to provide information to the Vice President, Sales and Research.
 10. Manages data archiving and SePRO's repository for analytical standards and other materials that are required for regulatory studies.
 11. Acts as the primary contact with business partners on regulatory matters.

KNOW-HOW

Technical and Functional Knowledge/Skill Abilities— At a minimum, a Bachelor of Science Degree in a scientific or related discipline. Advanced degrees and five+ years of regulatory experience in the field of Agricultural Pesticides are preferred. Experience with international registration preferred. Knowledge of the FIFRA regulatory process is required. Applicant should have good computer skills, including proficiency in excel, word, powerpoint, sharepoint, and other related programs. Personal characteristics of initiative, drive, organization, and attention to detail are important. Candidate should possess excellent verbal, written and listening skills to manage technical issues pertaining to regulatory processes, and have the ability to manage changing priorities and multiple projects at one time.

Human Relations—The position requires good communication skills as there is continuous interaction with the marketing/sales, supply chain/shipping, manufacturing, and communications departments. The ability to communicate with federal and state regulatory personnel and maintain excellent professional relationships are equally important. Therefore, good interpersonal skills of both written and oral communication are desired. Additionally, due to the workload required and the relatively small numbers of people involved, the position requires flexibility in thinking and action to accomplish given tasks and goals.

PROBLEM-SOLVING

Natures of thinking—Problems are generally technical in nature. Technical problems are largely non-repetitive and usually urgent and business imperative.

ACCOUNTABILITY

Freedom to Act—Research and Development strategies are agreed upon at the SePRO Management Level with input from others within the organization. The work needed to implement these strategies and other R&D responsibilities is carried out with minimal, but routine consultation with supervision. Freedom to set workload and time requirements are permissible with agreed upon permission by supervision, but must meet project goal timeframes.

Impact—Results are measurable in meeting timelines and resultant impact on meeting R&D goals and strategies as well as those of the business. The individual has a direct impact on results and an indirect impact on sales and growth of the organization.