JOB DESCRIPTION

Marrone Bio Innovations

Job Title: Regulatory Affairs Specialist, Study Monitor
Location of Position: MBI Headquarters, Davis, CA
Reports to (title): Regulatory Affairs Manager

SUMMARY:

We are currently looking for a Regulatory Affairs Specialist, Study Monitor to join our Regulatory group to support biological product dossiers to state, federal, and foreign regulatory agencies. Exact scope of responsibility will depend on chosen candidate's job skills and experience, which will dictate which products and/or projects are assigned to the Regulatory Affairs Specialist.

RESPONSIBILITIES AND DUTIES:

Essential Functions

- Plan, execute, and supervise internal and external GLP/GMP studies including but not limited to, mammalian toxicology, environmental toxicology, physical/chemical properties, and manufacturing processes. This may involve study protocol review, study site audits, interpretation of regulatory requirements, test results, and utilize these findings in product safety assessments.
- Create and update entries in project registration database to track registration status, manage projects and communicate changes to clients.
- Organize and maintain electronic and hard copy files of registration certificates and regulatory submissions, and study archives.
- Participate with colleagues in a team setting to continuously improve processes and procedures
- Provide regulatory support in the form of participating in regulatory meetings, answering inquiries related to regulatory dossiers and MBI products, and keeping up to date with regulatory guideline requirements and legislation changes.
- Provide project management and support, working directly with regulatory agencies, consultants and/or scientists to prepare regulatory labeling submissions, product registration applications and other client projects within established time frames.
- Assist MBI colleagues and MBI distribution partners in compiling regulatory dossiers for biopesticides, biofertilizers, biostimulants, and other plant health products

Other Duties

- Growth opportunity: US EPA and International product registrations and permits
- Other duties as assigned.

REQUIREMENTS:

- **Education:** Bachelor's degree or higher in a science-related field, preferably an agricultural or toxicology discipline
- **Experience:** Minimum of two years of experience in registration/regulatory/product certification
- Previous experience with CRO auditing, monitoring, or experimental development is a plus.
- Microbiology background a plus
- Good project management/organizational skills
- Proficiency in Microsoft Office software.
- High level of proficiency of the English language, both in verbal and written form.

- Proficient, both verbal and written, in Spanish is a plus
- Maintaining a valid driver's license and passport, and the ability to travel outside of the country.
- Ability to meet deadlines and work well under pressure
- Strong attention to details
- Professional demeanor
- Good knowledge of GLP/GMP/QA compliance requirements
- The individual should appreciate our entrepreneurial, fast-paced, agile, and dynamic work setting. He/she should be enthusiastic and energetic, goal-driven, and highly motivated to complete tasks in a timely, efficient manner. The candidate should also thrive in a strong team environment, be a self-starter and comfortable speaking up in company meetings. An individual who is positive, interactive, resourceful and creative in problem solving by thinking "out of the box" will be highly valued in this role.

Essential Physical and Mental Requirements
Physical Requirements: e.g.,

- Ability to sit at a desk for extended periods.
- Extensive use of computer keyboard, mouse and monitor.
- Ability to lift at least 20 pounds.
- Ability to work in a venue such as a Marrone Michigan Manufacturing, hotel or other organization's meeting room, conference, or convention space; possible inclusion of weekends.
- Overnight travel to annual meetings/conferences (typically up to 7 consecutive days) required; overnight travel to other meetings (typically 1-5 consecutive days); inclusion of weekends may be involved.
- Ability to walk through crop fields for extensive periods of time.
- Ability to drive or fly for extended periods of time to meet customers, or regulatory agencies at their locations.

Mental Requirements:

- Ability to work with frequent interruptions and changes in workload priorities, ability to prioritize tasks, ability to maintain confidentiality.

Travel:

- Ability to travel by car, train or air domestically and/or internationally. 10% -25% of the time.

MBI offers a comprehensive benefits package including a 401(k) plan with employer match, and a health plan including medical and dental coverage, life insurance coverage, long term disability, and a flexible spending account for dependent care and/or medical expenses.

The above is a list of essential duties and responsibilities for this position. This list is not all-inclusive and other duties may be assigned. This job description may be modified as needed.

MBI is an equal-opportunity employer. A pre-employment drug screen and background check will be required.

To apply please go to https://marronebioinnovations.com/company/careers/