

JOB DESCRIPTION

Job Title: REGULATORY AFFAIRS PROJECT MANAGER
Hiring Entity: ProFarm Group Inc
Reports to: DIRECTOR, GLOBAL REGULATORY AND GOVERNMENT AFFAIRS
SUPERVISES: N/A

SUMMARY:

ProFarm Group (PFG) is a subsidiary of Bioceres Crop Solutions, a global provider of biologically derived fertilizers, inoculants, crop traits, adjuvants, biostimulants and pesticides, serving the ever-expanding agricultural markets. PFG focuses on discovering, developing, and marketing nature-derived biostimulants, as well as pest management products from microbes and plant extracts for the effective control of invertebrate pests, weeds, and plant diseases.

We are currently looking for a Project Manager of Regulatory Affairs to join our Regulatory group to work with the Director of Regulatory Affairs and other regulatory department team members to register and manage ProFarm Group (PFG) product portfolio in the North America region. Exact scope of responsibility will depend on the chosen candidate's job skills and experience, which will dictate which products and/or countries are assigned to the Project Manager of Regulatory Affairs.

RESPONSIBILITIES AND DUTIES:

Major responsibilities:

- Lead the regulatory process and submission of PFG products in the North America region and/or others as needed.
- Lead the preparation and submission of 3rd party certifying agencies and compliance authorities
- Liaise with regulatory agencies, industry groups, and other stakeholders.
- Manage all dossier building activities for PFG products in country, state, etc. as applicable.
- Coordinate and manage movement, transport, and release requirements for MBI products falling under Plant Protection Act regulations or similar.
- Coordinate and manage regulatory approvals for international experimental use permits and associated import permit requirements for product development or registration purposes.
- Assemble and coordinate state regulatory dossiers for biopesticides, biofertilizers, biostimulants and/or other plant health products.



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- Coordinate outreach to commodity and other user groups to support registrations for PFG products to comply with federal, state, and/or county regulations. Including, but not limited to, attendance and representation at public functions.
- Coordinate with Product Development and commercial team to ensure adequate field trials and product labels are completed to support efficacy requirements and supporting marketing materials in key states and countries.
- Coordinate and manage projects with R&D teams to develop, expand, and/or resolve queries from regulatory agencies or certifiers. Intra-departmental communication is heavily required.
- Coordinate projects with outside consultants as assigned.
- Support and help the team with regulatory strategy in regions as assigned timelines and requirements for development tasks needed for submissions.
- Other duties as assigned.

MINIMUM QUALIFICATIONS:

- BS, MS, or PhD in a science-related field, preferably an agricultural discipline, with a minimum of three years' experience in registration/regulatory affairs
- Experience with regulatory agencies and knowledge of regulatory procedures, particularly USEPA
- Previous experience with biopesticide registration a plus
- Previous experience with USDA APHIS PPQ permitting a plus
- Microbiology background a plus
- Previous experience with aquatic pesticides and US Clean Water Act a plus
- Good project management/organizational skills
- Excellent communication skills, both written and oral
- Fluency in Spanish and/or Portuguese a plus
- Ability to meet deadlines and work well under pressure
- Strong attention to details
- Professional demeanor
- Computer literate
- Some knowledge of GLP/GMP/QA compliance requirements is a plus

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,**



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resourceful and creative in problem solving by thinking "out of the box" will be highly valued in this role.

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