Global Regulatory Manager

Aphea.Bio is **a leading R&D company** that is dedicated to food security and ensuring a safe and healthy food chain. We aim to provide novel science-based solutions to build the **agriculture of the future: sustainable, reliable and profitable**. Aphea.Bio focuses on the exploitation of natural, beneficial interactions that occur between microorganisms and plants. We discover and develop new biology-based agricultural products for crop protection and crop.

Aphea.Bio is based in **Ghent**, Belgium and embedded in the largest European Agro-Biotech valley.

As **Global Regulatory Affairs Manager** at Aphea.Bio, you will be responsible to implement the regulatory strategy for our microbial biocontrol and biostimulant portfolio in North America, Brazil, and Europe. Working in a cross-functional team, the successful candidate will be responsible for creating submission dossiers and managing projects to ensure timely and successful regulatory submissions, as well as supporting the early product development stages through regulatory risk assessments and literature searches.

Key Responsibilities:

- Implementing the regulatory strategy for our microbial biocontrol and biostimulant products in North America, Brazil, and Europe, including identification of key regulatory requirements, timelines, and stakeholders.
- Prepare and submit regulatory filings, including registration dossiers, notifications, and amendments to regulatory authorities in North America, Brazil, and Europe.
- Manage projects to ensure timely and successful regulatory submissions, including coordinating with cross-functional teams, identifying and mitigating risks, and tracking progress against project timelines.
- Collaborate with cross-functional teams, including R&D, manufacturing, and commercial teams, to ensure that regulatory strategies are aligned with business objectives.
- Stay up-to-date with changes in regulatory requirements and guidelines in North America, Brazil, and Europe, and implement changes as necessary.
- Provide regulatory guidance and support to internal stakeholders, including R&D, manufacturing, and commercial teams.
- Develop and maintain relationships with regulatory authorities in North America, Brazil, and Europe to ensure open communication and effective resolution of issues.

Requirements:

- Relevant Master's degree or PhD and at least 4 years of relevant industry experience (preferably in biologicals).
- Strong project management skills, including ability to manage multiple projects simultaneously and prioritize tasks to meet deadlines.
- Strong knowledge of relevant regulations in the EU, additional geographies are a benefit.
- Hands-on experience with preparing and submitting regulatory filings.
- Ability to conduct literature searches according to EFSA guidelines.
- Excellent communication and interpersonal skills, with ability to work independently.
- Strong analytical and problem-solving skills.

Other skills:

- Computer skills: proficiency in Word, PowerPoint and Excel applications
- You are fluent in (Dutch and) English, both written and verbal
- You are dynamic, flexible and committed to results
- You combine a scientific background with a hands-on attitude
- You possess good communication skills

Motivated applicants should send their CV, including a cover letter to Veerle.vancleemput@aphea.bio, charlotte.klank@aphea.bio and David.ingham@aphea.bio.