

## Associate Director, Regulatory Affairs Pharma Safety & Efficacy

Boehringer Ingelheim is currently recruiting for an Associate Director, Regulatory Affairs Pharma Safety & Efficacy position. The ideal candidate would be Veterinarian with food animal experience working with regulatory agencies. The preferred working locations are St. Joseph, MO or Duluth, GA, but would consider candidates who want to work remote.

Direct inquiries about the position or application process can be sent to Mike Kirby ([michael.kirby.ext@boehringer-ingelheim.com](mailto:michael.kirby.ext@boehringer-ingelheim.com))

Applicants are encouraged to apply directly this position:

[Associate Director, Regulatory Affairs Pharma Safety & Efficacy](#)

### **Description:**

Act as RA core- or sub team member in projects as well as in program teams. Anticipate changes in pertinent regulations and evaluate impact on projects/existing products. Define sound regulatory strategies for assigned products/projects within the team and ensure regulatory compliance with regard to safety and efficacy.

The position will link the safety and efficacy regulatory team with internal stakeholders and external stakeholders (regulatory agencies) to ensure comprehensive synergies between regulatory, research, development and business activities in accordance with the strategic plan of the company.

As an employee of Boehringer Ingelheim, you will actively contribute to the discovery, development and delivery of our products to our patients and customers. Our global presence provides opportunity for all employees to collaborate internationally, offering visibility and opportunity to directly contribute to the companies' success. We realize that our strength and competitive advantage lie with our people. We support our employees in a number of ways to foster a healthy working environment, meaningful work, diversity and inclusion, mobility, networking and work-life balance. Our competitive compensation and benefit programs reflect Boehringer Ingelheim's high regard for our employees.

### **Duties & Responsibilities:**

- Responsibility for the safety and efficacy part of the dossier for new veterinary products as well as life-cycle management of existing products for assigned projects/products in US and other markets, when applicable. Responsibility for coordinating technical input for Freedom of Information Summary and product labeling for assigned projects.
- Work in project teams in accordance with the project governance model to drive Research Profile/Target Product Profile and Quality Target Profile.
- Provide consistent regulatory advice to project teams regarding the pathways and approaches to regulatory approvals with details pertaining to time to market, costs, and robustness/marketability of each approval. Serve as RA core team member for project teams. The role of a RA core team member includes steering all regulatory aspects of development and includes leading of sub teams.
- Serve as Subject Matter Expert on the current US regulatory environment and potential trends. Recommend and communicate proactive approaches to regulatory issues. Facilitate partnerships, both formal and informal, with key regulatory agency review staff.
- Participate in due diligence processes by providing regulatory assessment and expertise.

- Responsibility to evaluate product dossiers for regulatory compliance and suitability for registration.
- Pro-active representation of RA for infrastructural processes and projects. Responsible for the successful update of regulatory tools as defined. Lead/support specific infrastructural projects as assigned.
- Active representation of company at external functions in order to drive agenda with BI best interests in mind. Communication interface and influencer with the veterinary regulatory authorities and industry associations. Responsible for proactively seeking contact with regulatory authorities directly, as appropriate, and positioning BI as a trusted and innovative partner (key account management). Ensure a balanced relationship with the authorities.

**Requirements:**

- Advanced degree (Doctor of Veterinary Medicine or PhD in relevant discipline) from an accredited institution with minimum five (5) years related experience in Regulatory Affairs strategy/execution; or Master's degree from an accredited institution in relevant scientific discipline with minimum ten (10) years' experience in Regulatory Affairs strategy/execution
- At least five (5) years in Regulatory Affairs positions, or equivalent in the pharmaceutical industry. Must include a minimum of two to three (2-3) years conveying exposure to authorities (e.g. in new product development or complex maintenance projects, leadership of RA subteams).
- Regulatory Affairs or equivalent pharma experience in animal health is required including prior FDA/CVM/EPA interaction.
- Intrapreneurial spirit while being rigorous and disciplined with compliance requirements.
- Demonstrated ability to successfully collaborate in a global organization and manage a full workload across multiple projects.
- Effective communicator with good negotiation and interpersonal skills and the ability to form productive working relationships at all levels across disciplines and nationalities.
- Able to meet stringent time and quality demands and to initiate, develop and implement systems and strategies to ensure rapid and successful outcomes.
- Self-motivated with a high degree of initiative, commitment and persistence.
- Well-developed organizational capabilities.
- Strong team player who is collaborative with the mission of BI, but able to drive change.
- Ability to handle high workloads and understanding of cultural differences
- Excellent command of English language, both written and spoken
- Sound knowledge of the legal requirements for approval of veterinary medicinal products.
- Knowledge in international product registration and/or product development is desired.
- Awareness of the industry/direct competitor's activities.
- Sound knowledge in relevant Regulatory Affairs areas. Ability to understand and anticipate regulatory trends.
- Sound knowledge and established understanding of regulatory legislation and requirements for the development and maintenance of veterinary products with a focus on safety and efficacy aspects.

**Eligibility Requirements:**

- Must be legally authorized to work in the United States without restriction.
- Must be willing to take a drug test and post-offer physical (if required)
- Must be 18 years of age or older

### **Who We Are:**

At Boehringer Ingelheim we create value through innovation with one clear goal: to improve the lives of patients. We develop breakthrough therapies and innovative healthcare solutions in areas of unmet medical need for both humans and animals. As a family owned company we focus on long term performance. We are powered by 50.000 employees globally who nurture a diverse, collaborative and inclusive culture. Learning and development for all employees is key because your growth is our growth.

Want to learn more? Visit [www.boehringer-ingelheim.com](http://www.boehringer-ingelheim.com) and join us in our effort to make more health.

Boehringer Ingelheim, including Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim USA, Boehringer Ingelheim Animal Health USA Inc., Boehringer Ingelheim Animal Health Puerto Rico LLC and Boehringer Ingelheim Fremont, Inc. is an equal opportunity and affirmative action employer committed to a culturally diverse workforce. All qualified applicants will receive consideration for employment without regard to race; color; creed; religion; national origin; age; ancestry; citizenship status, marital, domestic partnership or civil union status; gender, gender identity or expression; affectional or sexual orientation; pregnancy, childbirth or related medical condition; physical or psychiatric disability; veteran or military status; domestic violence victim status; genetic information (including the refusal to submit to genetic testing) or any other characteristic protected by applicable federal, state or local law.