

Akston Biosciences has an immediate opening for a **Director/Sr. Manager, Regulatory Affairs – Biologics (USDA)**

**Title** Director/Sr. Manager, Regulatory Affairs – Biologics (USDA)

**Company** We are an innovative biotech company focused on developing **protein therapeutics (biologics) for the USDA-regulated pet health market**. Our mission is to advance **novel veterinary biologics** that improve animal health and well-being. We foster a **collaborative and dynamic work environment**, where your expertise in regulatory affairs will play a crucial role in shaping the success of groundbreaking therapies.

### Position Summary

We are seeking an experienced **Director /Sr. Manager of Regulatory Affairs** to lead and oversee all regulatory activities for our **USDA-regulated biologics programs**. Reporting to the **VP of Quality Assurance & Regulatory Affairs**, this individual will serve as the primary liaison with **USDA/CVB**, ensuring regulatory compliance and timely approvals. The ideal candidate will have deep expertise in veterinary biologics regulatory strategy, submission processes, and regulatory agency interactions.

### Primary Duties

- Lead **regulatory affairs** initiatives for **USDA-regulated** biologics and serve as the primary point of contact with **USDA/CVB**.
- Develop and execute **regulatory strategies** to support product development and approval.
- Manage **regulatory submissions**, ensuring compliance with **USDA/CVB** requirements and timely approvals.
- Collaborate with **consultants and internal teams** to prepare, review, and submit regulatory documents to USDA/CVB.
- Provide regulatory guidance to **R&D, manufacturing, and quality teams** to ensure compliance with **9 CFR guidelines** and USDA/CVB expectations.
- **Author and review** regulatory submissions, including CMC sections, compliance reports, and risk assessments.
- Monitor **regulatory updates**, communicate changes, and develop proactive compliance strategies.
- Prepare responses to **regulatory queries**, ensuring commitments are met effectively and efficiently.
- Represent the company in **regulatory meetings and discussions** with USDA/CVB and other stakeholders.

### Other Responsibilities & Skills

- Apply **analytical thinking and risk-based management** to drive regulatory strategies.
- Demonstrate **strong regulatory writing skills**, ensuring accuracy and strategic alignment.

- Manage multiple projects and regulatory submissions, utilizing tools such as **Microsoft Excel** and **Microsoft Project**.
- Work independently in a **fast-paced environment**, adapting to shifting priorities and deadlines while collaborating with cross-functional teams.
- Exhibit **excellent communication and interpersonal skills** to foster productive collaboration.

#### Qualifications

- Bachelor's degree in a **STEM field** (Life Sciences preferred).
- Advanced training or a **degree in Regulatory Affairs** is highly desirable.

#### Experience

- **Minimum of 8 years** in the pharmaceutical/biotech industry, including **at least 5 years in regulatory affairs** for biologic therapeutics.
- **At least 3 years of direct experience with USDA-regulated submissions.**  
**Expertise in:**
  - **Regulatory strategy and writing**, including **CMC documentation** and biologics submissions.
  - Working with **regulatory authorities** (USDA, FDA-CVM, EMA) across various development phases.
  - **9 CFR guidelines**, USDA memos, and **GMP manufacturing** requirements for biologics.

#### Compensation

- **Competitive salary**, based on experience.
- **Eligibility for company stock options and comprehensive benefits.**

#### Other

- **On-site** role based in **Beverly – Lexington, MA.**
- **Hybrid work arrangement** possible.

For more information, see [www.akstonbio.com](http://www.akstonbio.com).

If you are passionate about **veterinary biologics and regulatory strategy** and want to make a **meaningful impact** in a growing biotech company, we encourage you to apply!

**Apply Now:** Candidates should send CV and cover letter to [careers@akstonbio.com](mailto:careers@akstonbio.com)