Akston Biosciences Corporation
100 Cummings Ctr., Ste. 454C
Beverly, Massachusetts 01915

Office: 978-969-3381
Fax: 978-522-8499
e-mail: info@akstonbio.com

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

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

Company Akston is a biotech company built for pets. Using our proprietary Ambifect® Fc-fusion protein platform, we develop immuno-enhancing and targeted protein treatments that aim to reduce treatment frequency while enhancing efficacy. Backed by a vertically integrated structure and state-of-the-art GMP biologics facility, we accelerate development from discovery to commercial manufacturing – ensuring innovation reaches veterinarians and the pets we love faster and more efficiently. Learn more at www.akstonbio.com.

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.

18-March-2025

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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, MA.
- Hybrid work arrangement possible.

Apply Now: Candidates should send CV and cover letter to careers@akstonbio.com

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