AKSTON BIOSCIENCES

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 Biosciences has an immediate opening for a **Director/Sr. Manager, Clinical Development – Biologics (USDA)**

Title **Director/Sr. Manager, Clinical Development – 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 Clinical Development** to lead and oversee all **clinical development activities** for our **USDA-regulated biologics programs**. This role will be responsible for designing and managing **clinical studies**, coordinating with **CROs, study sites, and regulatory agencies**, and ensuring regulatory compliance. The ideal candidate will bring **extensive experience in veterinary biologics clinical development**, regulatory strategy, and **overseeing clinical studies** for protein therapeutics.

Primary Duties

- Lead **clinical development and study execution** for USDA-regulated biologic therapeutics.
- Develop **clinical study strategies** for novel veterinary biologics programs.
- Oversee the design, implementation, and management of **clinical studies**, ensuring compliance with **USDA regulatory requirements**.
- Collaborate with **CROs, study sites, investigators, and consultants** to review protocols and oversee data collection, analysis, and report generation.
- **Author and review** key clinical documents, including **clinical study plans, protocols, and reports** in accordance with **USDA guidelines**.
- Conduct **data analysis and statistical assessments** to ensure regulatory alignment and generate **final study reports** for submission.
- Prepare responses to **regulatory queries**, ensuring commitments are met in a timely and effective manner.
- Provide **clinical insights and guidance** to internal teams, including R&D and regulatory affairs.

Other Responsibilities & Skills

- Apply **analytical thinking and risk-based management** to guide clinical development strategy.
- Demonstrate **strong technical writing** skills, with attention to detail and regulatory alignment.
- Manage **clinical development projects effectively**, leveraging tools like **Microsoft Excel and Microsoft Project**.

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- Work independently in a **fast-paced, evolving environment**, adapting to shifting priorities and deadlines.
- Exhibit **excellent communication and interpersonal skills** to foster productive collaboration across internal and external stakeholders.

Qualifications

- **Advanced degree (DVM, PhD, or equivalent)** in a relevant scientific discipline.

Experience

- **Minimum of 10 years in the pharmaceutical/biotech industry, including at least 5 years in veterinary biologics clinical development with a focus on USDA-regulated products.**

Expertise in:

- **USDA regulatory requirements** for veterinary biologics clinical studies.
- Working with **CROs, clinical study sites, and regulatory agencies**.
- **Clinical data analysis, statistical assessments, protocol development, and study report writing**.
- Regulatory interactions with **USDA/CVB** throughout the clinical development process.

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.

If you are passionate about **veterinary biologics and clinical development** 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