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, Clinical Development – Biologics (USDA)**

Title Director/Sr. Manager, Clinical Development – 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 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.
- 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.

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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, MA.
- Hybrid work arrangement possible.

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