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

Title	**Regulatory Affairs Sr. Manager / Director**
Reporting	Reports to VP, Quality Assurance and Regulatory Affairs
Company	Akston Biosciences is inventing, developing, and manufacturing breakthrough protein therapeutics for Companion Animal Health. Our integrated capabilities, from discovery to commercial manufacturing, give us unique advantages. Our innovations and strategic partnerships enhance opportunities for success. For more information, see www.akstonbio.com.
Qualifications	Bachelor's degree in a STEM field with a preference for life sciences. Advanced training/degree in Regulatory Affairs is highly desirable.
Experience	Minimum of 8 years of pharmaceutical industry experience, including 5 years of experience in CMC Regulatory Affairs projects and regulatory submissions comprising biologic therapeutics. Should be well-versed in regulatory strategy and regulatory writing and have experience as a co-author for regulatory documents, CMC, and submissions with a specific focus on veterinary biologics. Experience in working with regulatory authorities such as FDA, FDA-CVM, USDA, and EMA, across all phases of clinical development and regulatory submissions for approval of biologic therapeutics. Strong knowledge and proficiency in ICH, FDA, and EMA guidelines, and familiarity with GMP/GCP/GLP compliance.

Primary Duties

- Represents Regulatory Affairs activities among cross-functional project teams and functions as the primary contact on CMC regulatory aspects of the projects between Akston and its partner companies.
- Collaborates with partner companies and consultants for the timely preparation, review, and submission of documents to regulatory authorities. Effectively communicates with internal and external team members, senior leaders, and key stakeholders on the status of CMC regulatory submissions.
- Leads and/or co-authors the preparation of information packages for CMC regulatory submissions and concurrence protocols and reviews these packages for conformance with established regulatory requirements and expectations.
- Supports cross-functional workstreams in support of company IND/INAD applications, CTAs, and new biologics applications (NDA/ANDA/BLA) and submissions. Manages routine regulatory submission workflows.
- Assists in the preparation of responses to queries from regulatory authorities and ensures commitments are addressed diligently and effectively before submission.

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Other Responsibilities & Skills

- Exhibit strong analytical thinking skills with demonstrated experience applying risk-based management principles, providing risk-based strategic and tactical guidance, and writing risk assessments to meet the regulatory submission goals.
- Exhibit strong regulatory document writing skills and strong analytical and strategic thinking skills with attention to detail.
- Demonstrate project and regulatory submission management skills, including the use of Microsoft Excel and Microsoft Project.
- Demonstrate an ability to work independently and thrive in a fast-paced environment, adapt to changing priorities and challenging timelines, and interface with collaborators and consultants.
- Exhibit strong communication and interpersonal skills.

Compensation	Commensurate with skills and experience with eligibility for company benefit plans.
Other	Must work onsite in Beverly MA
Contact	Candidates should send CV and cover letter to careers@akstonbio.com.