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 **Regulatory Affairs Specialist**

Title **Regulatory Affairs Specialist**

Primary Duties

- Represents Regulatory Affairs activities among cross-functional project teams at Akston and functions as the primary contact on CMC regulatory aspects of the projects between Akston partner companies and serves as the project manager for biologics projects.
- Collaborates with partner companies and consultants, and leads the timely preparation, review, publishing 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. With minimal supervision, manages routine regulatory submission workflows.
- Assists in preparation of responses to queries from regulatory authorities and ensure commitments are addressed diligently and effectively before submission.

Other Responsibilities & Skills

- Be a process minded and analytical thinker with demonstrated experience applying risk management principles, writing risk assessments, and providing risk-based strategic and tactical guidance to meet the regulatory submission goals
- Exhibit strong regulatory documents writing skills, 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 and ability to adapt to changing priorities and challenging timelines, and to interface with collaborators and consultants
- Exhibit strong communication and interpersonal skills

Qualifications

- A BA/BS degree in life sciences. Advanced training/degree in Regulatory Affairs is highly desirable.

Experience

- A minimum of 5 years pharmaceutical industry experience, including 3 years of experience in CMC Regulatory Affairs projects comprising biologic therapeutics.
- Should be well-versed in regulatory strategy and regulatory writing and have experience as

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co-author for regulatory documents, CMC, and submissions.

- Experience in working with regulatory authorities such as FDA, FDA-CVM, USDA, EMA, and/or Health Canada 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.

Compensation Title and pay commensurate with skills and experience, eligibility for company benefit plans.

Other Must live within commuting distance of Beverly, MA.

Company Akston Biosciences Corporation invents, develops, and manufactures breakthrough protein therapeutics for Companion Animal Health. We leverage our novel Ambifect™ Fc-fusion platform to develop and manufacture new classes of therapeutics. Additionally, Akston serves as a Contract Manufacturing Organization (CMO) for other Animal Health companies through production and manufacturing facilities that are dedicated to Animal Health. Our facilities, along with our research and process development laboratories, are located in Beverly, Massachusetts.

Akston has an immediate opening for a **Regulatory Affairs Specialist** position in Beverly, MA. For more information, see www.akstonbio.com.

Contact Candidates should send CV and cover letter to careers@akstonbio.com