Akston Biosciences has an immediate opening for a **Senior Quality Assurance Specialist**

**Title Senior Quality Assurance Specialist**

**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 a highly skilled Senior Quality Assurance (QA) Specialist to lead and support critical Quality Assurance activities within our biologics manufacturing operations. Reporting to the VP of Quality Assurance & Regulatory Affairs, this senior-level role will play a key part in maintaining and improving our Quality Management System (QMS) while ensuring compliance with USDA and FDA regulations.

The ideal candidate brings extensive expertise in QA operations, regulatory compliance, and biologics manufacturing, with a strong ability to drive quality initiatives and uphold the highest industry standards. This role offers an opportunity to contribute to the success of innovative biologics products in a dynamic and growth-focused environment.

**Primary Duties**

* Work independently and drive quality objectives by developing and implementing strategies to maintain and enhance Quality System compliance.
* Proactively identify and resolve quality issues by recommending and executing process improvements that align with long-term quality initiatives.
* Lead and manage key quality processes, including change control, deviations, investigations (OOS), CAPA implementation, and effectiveness monitoring to ensure continuous improvement.
* Identify and address compliance risks related to GMP regulations, proposing and implementing effective resolution plans.
* Review and approve critical quality documentation, including but not limited to equipment IQ/OQ, MBRs, PBRs, manufacturing protocols, facility documents, EM reports, vendor qualifications, change notifications, validation reports, and stability reports.
* Monitor and assess quality performance across GxP operations both internally and at external suppliers/vendors, driving corrective actions and continuous improvements.
* Lead and support training initiatives by onboarding new QA Associates, contributing to training programs, and ensuring compliance with training management systems.
* Participate in internal audits and ensure timely follow-ups, while also assisting in vendor audits to maintain supplier compliance and quality standards.

**Other Responsibilities & Skills**

# Strong writing skills, ensuring clarity, accuracy, and alignment with quality and compliance objectives.

# Excellent organizational abilities, with the capacity to manage multiple priorities, adapt to evolving deadlines, and perform effectively in a fast-paced, dynamic environment.

# Proficiency in project management, including tracking and managing regulatory submissions using tools such as Microsoft Excel and Microsoft Project.

# Ability to work independently while demonstrating flexibility in handling shifting priorities and collaborating effectively across cross-functional teams.

# Exceptional communication and interpersonal skills, fostering productive collaboration across internal and external stakeholders.

# Qualifications

* Bachelor’s or Master’s degree in Life Sciences, preferably in Biology, Biomedical Sciences, Pharmaceutical Sciences, or a related field.

**Experience**

* Minimum of **5 years of industry experience in pharmaceutical or biotech manufacturing**, with at least **3 years of direct Quality Assurance (QA) experience** supporting GMP/GLP compliance.
* Strong proficiency in Quality Systems and QA activities within a regulated pharmaceutical or biotech environment, ensuring GxP compliance.
* Hands-on experience with quality assurance tools, methodologies, and best practices, with a deep understanding of risk management and continuous improvement principles.
* Comprehensive knowledge of global regulatory standards, including FDA, EMA, and other applicable industry regulations governing pharmaceutical and biologics manufacturing.

**Compensation**

* **Competitive salary**, based on experience.
* **Eligibility for company stock options and comprehensive benefits.**

**Other**

* **On-site** role based in **Beverly – Lexington, MA**.

For more information, see [www.akstonbio.com.](http://www.akstonbio.com/)

If you are passionate about **veterinary biologics and quality assurance** 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