AKSTON BIOSCIENCES

Akston Biosciences Corporation
100 Cummings Ctr., Ste. 454C
Beverly, Massachusetts 01915

Office: 978-969-3381
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e-mail: info@akstonbio.com

Akston Biosciences has an immediate opening for **Senior Quality Assurance (QA) Specialist**.

Title **Senior Quality Assurance Specialist**

Primary Duties

- Perform QA review of controlled documents including SOPs, batch records, analytical records, warehouse and material records, product specifications and release documents, CoAs, deviation reports, change control documents, equipment records and logs, qualification/ validation reports, cleaning records, pest control logs, and environmental and microbial monitoring reports
- Write SOPs and establish QA procedures to ensure quality operations in the regulated company facilities (manufacturing unit, GMP area and QC/GLP laboratories)
- Write additional quality system documents such as quality policies and memos, inspection/audit reports, and risk assessment protocols and reports
- Coordinate quality activities and identify and resolve quality problems in GMP/GLP units at Akston or with external suppliers/vendors, and help implement continuous improvements in quality procedures
- Identify, investigate, and report deviations, non-conformance and out-of-specification incidents, and help implement CAPA tools for minimizing such incidents
- Establish procedures for change control process and ensure controlled implementation of all GMP and GLP related changes
- Conduct quality inspections and internal audits of manufacturing units and analytical laboratories to ensure regulatory and quality compliance
- Assist in qualification and approval of vendors and suppliers
- Assist in conducting audits of external vendors/suppliers, CROs, and CMOs to ensure quality and regulatory compliance, and provide support during inspections or audits conducted at Akston by external sources
- Assist in conducting risk analysis, and implementing risk management procedures in critical areas
- Implement document management and control activities in the quality system including collection, distribution, storage, scanning/imaging, archival and retrieval of controlled documents
- Establish and implement procedures to ensure the quality of raw materials and other critical materials and their storage and use in manufacturing
- Monitor equipment and facility management procedures (IQ/OQ/PQ, maintenance, calibrations) to ensure quality compliance
- Assist in training of staff in quality system procedures and operations

Other Responsibilities & Skills

- Strong communication and interpersonal skills
- Good organizational skills with ability to adapt to changing priorities, to multi-task in a fast-paced and dynamic environment and to meet challenging timelines
- Ability to develop solutions to complex quality problems and establish processes to continuously improve and streamline existing quality procedures

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- Communicate with outside vendors to learn and implement new technologies, where applicable, into the company's processes
- Demonstrate ability to understand and interpret data and its practical applications

Qualifications

A master's degree or bachelor's degree in life sciences, preferably majoring in Biology, Biomedical, Pharmaceutical Sciences or relevant field and 5-10 years of work experience in pharmaceutical or biotech industries with minimum of 4 year of QA experience in support of GMP/GLP is required. Formal training and expertise in Quality Systems or QA operations and applicable regulations is highly desirable.

Experience

The successful candidate shall**:**

- Demonstrate in-depth knowledge, proficiency, and experience in Quality Systems and QA activities in regulated pharmaceutical environment.
- Have adequate experience in QA functions and implementation of quality system in GxP environment (including manufacturing units and quality control laboratories) such as conducting internal audits and inspections, conducting external audits, hosting audits, conducting investigations, deviation management, change control procedures, CAPA implementation, risk assessment and management, product recall procedures, employee training, vendor/supplier qualification, document control, and trend monitoring etc.
- Have experience in quality review of SOPs, manufacturing batch records, analytical reports, product specification records, deviation reports, cleanroom environmental and microbial monitoring records/reports, and qualification/validation reports (e.g., facility, equipment, process, and cleaning validation).
- Have experience in writing quality system documents such as quality policies and memos, SOPs, inspection/audit reports, risk assessment reports etc.
- Have knowledge of FDA, EMEA, and other applicable industry and quality regulations related to pharmaceutical industry.
- Demonstrate strong skills with common software programs such as Microsoft Word, Excel, PowerPoint and MS Project; and a familiarity with analytical and statistical analysis software

Compensation

Pay commensurate with skills and experience, eligibility for company benefit plans.

Other

Must live within commuting distance of Beverly, MA.

Company

Akston Biosciences leverages its novel fusion protein platform to develop and manufacture new classes of biologics, including autoimmune disease therapies, ultra-long-acting insulins, and vaccines. Akston has built a diverse pipeline of therapeutic candidates for use in both human and animal health. Akston has an immediate opening for **Senior Quality Assurance (QA) Specialist** position for the company located in Beverly, MA. For more information, see www.akstonbio.com.

Contact

Candidates should send CV and cover letter to careers@akstonbio.com or t.sathi@akstonbio.com