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 **Quality Assurance Associate / Specialist**

Primary Duties

- Perform quality review of GMP documents including SOPs, batch records, analytical records/reports, warehouse and material records, product specifications and release documents, deviation reports, change control documents, qualification/validation reports, and stability study reports
- Write SOPs and establish QA procedures to ensure quality operations in the regulated company facilities (manufacturing unit, GMP area and QC/GLP laboratories)
- Coordinate quality activities with manufacturing and quality control units. Identify and resolve quality problems in GxP units at Akston or with external suppliers/vendors, and help implement continuous improvements in the quality procedures
- Identify deviations, non-conformance, and out-of-specification incidents, and assist in investigating and implementing CAPA tools for minimizing such incidents
- Conduct routine inspections of manufacturing processes, analytical processes, and QC procedures and audits of records/documents to ensure regulatory compliance
- Assist in conducting internal audits of manufacturing units and analytical laboratories to ensure regulatory and quality compliance
- Assist in implementation of 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
- Assist in monitoring equipment calibrations, PM and IQ/OQ/PQ and maintaining such records
- Assist in training of staff in quality 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
- 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

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Qualifications

A bachelor's degree or master's degree in life sciences, preferably majoring in Biology, Biomedical, Pharmaceutical Sciences or relevant field and 1-5 years of work experience in pharmaceutical or biotech industries with minimum of 1 year of QA experience in support of GMP/GLP is required. Proficiency and knowledge in quality system operations and applicable regulations related to GxP is preferred.

Experience

The successful candidate shall**:**

- Demonstrate proficiency in quality systems and QA activities in regulated pharmaceutical environment
- Have experience in QA functions and implementation of quality procedures for GxP compliance
- 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
- Have experience in writing of quality documents and procedures (e.g. SOPs).
- 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 two immediate openings for **Quality Assurance (QA) Specialist/Associate** positions 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