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 **Pharmaceutical - Quality Assurance Specialist**

Position Akston has an immediate opening for **Quality Assurance (QA) Specialist** position for the company located in Beverly, MA.

Company Akston Biosciences is developing and manufacturing new classes of biologics using our novel fusion protein platform. We have built a diverse pipeline of therapeutic candidates including a clinical stage COVID-19 vaccine, ultra-long-acting insulins and autoimmune disease therapies.

Primary Duties

- Perform QA review of controlled documents including SOPs, batch records, analytical records, warehouse and material records, product release documents, CoAs, deviation reports, change control documents, equipment records and logs, qualification/ validation reports, 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)
- 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
- 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 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

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 with 5-10 years of work experience or master's degree with 3-5 years of work experience in Biology, Biomedical, or Pharmaceutical Sciences with minimum of 3 year of QA experience in pharmaceutical or biotech industries is required. Formal training and expertise in GMP/GLP Quality Systems 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, medical/dental, retirement plan, 3 weeks' vacation and paid holiday/sick time, tuition reimbursement, patent incentive plan, and equity incentive plan.

Other

Must live within commuting distance of Beverly, MA.

Contact

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