

Akston Biosciences has an immediate opening for a **Quality Control Associate I/II, Raw Materials**

Title **Quality Control Associate I/II, Raw Materials**

Primary Duties

- Responsible for routine and non-routine testing of incoming and Akston made raw materials and in-process materials in accordance with GxP protocols and SOPs. This may include, but is not limited to, pH, conductivity, osmolality, endotoxin, and appearance testing.
- Responsible for the daily GMP receipt, quarantine, and/or release of raw materials and other controlled materials according to SOPs and Material Specifications in GMP raw materials warehouse or storage location.
- Inspect and sample routine and non-routine raw material consignments in accordance with approved specifications in a cGMP-compliant manner. Follow appropriate safety protocols when working with hazardous materials.
- Support the shipment of samples to approved contract laboratories for testing.
- Accurately document results from Akston or external vendors and contracted organizations as related to raw material testing and release, and evaluate against internal raw material specifications. Accurately follows applicable written procedures.
- Assist with approval and/or approve Akston-made intermediates and products in manufacturing facility and/or special storage areas. Includes inspection of sterilization records and appropriate batch record results.
- Write, revise and review material specifications, change controls, deviations, and SOPs.
- Assist with change notifications associated with raw materials and help to implement necessary change controls or changes.
- Work with Manufacturing Materials staff to manage and improve evolving inventory-control systems for the GMP warehouse.
- Communicate inter-departmentally, as necessary with outside contacts to resolve compliance and technical issues.

Other Responsibilities & Skills

- Help maintain laboratory equipment to ensure proper working order and troubleshoot malfunctions when needed; this includes routine cleaning and maintenance, calibrations, and IQ/OQ/PQ of equipment in sampling areas or other relevant areas.
- Assist in management and documentation of outsourced testing in support of process/product testing for Internal Raw Materials Testing Program and supplier qualification memos and reports.
- Must be extremely detail-oriented, with solid observational skills, including the ability to efficiently and identify inconsistencies in labeling and defects in packaging or materials.

- Capable of executing cGMP training, and working in compliance with cGMPs, effectively demonstrating an understanding of cGMP's relevant to role.
- Able to keep neat and detailed records of data and appropriately document results according to established guidelines, and notify management of discrepancies and defects in a timely manner.
- Ability to work with and around chemicals, and adopt chemical hygiene practices to ensure safe handling of chemicals, and use PPE as necessary to ensure proper safety practices are used, and identify safety risks.
- 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.
- May be asked to perform additional QC laboratory testing (e.g., microbial testing) if needed.

Qualifications

- A minimum of a bachelor's degree in Chemistry, Microbiology, Biology, Biomedical, Pharmaceutical Sciences or related field, preferably with 0 to 2 years of work experience in a GMP environment in the pharmaceutical or biotech industries. Equivalent combination of education, training and relevant work experience may be considered.
- Quality Control Laboratory or Raw Materials Testing experience in support of cGMP/GLP is a plus.
- Display strong interpersonal, oral and written communication skills, ability to effectively communicate with peers and area management.
- Works under general supervision but routinely performs task independently with minimal supervision.
- Ability to lift, pull, or push materials requiring 50 lbs of force.

Experience

The successful candidate shall:

- Formal training and previous work experience in a cGMP or quality control laboratory, including experience with basic raw materials testing techniques such as pH and conductivity, highly desirable.
- Demonstrate familiarity with Microsoft Word, Excel, and PowerPoint
- Experience with Microbiological testing (e.g., Bioburden, Environmental Monitoring) is a plus.
- Some experience in at least one of the following areas: writing technical reports, validation reports and SOPs; environmental monitoring; working in an aseptic environment (e.g., clean room or sterile hood) is a plus.
- Ability to train and work within environmental clean room or laboratory settings.

- 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 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 a **Quality Control Associate** 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