AKSTON BIOSCIENCES

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

Office: 978-969-3381
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Akston Biosciences has an immediate opening for a **Quality Control Manager**.

Title: Quality Control Manager

Akston Biosciences Summary

Akston Biosciences Corporation leverages its novel fusion protein platform to develop and manufacture new classes of biologics, including vaccines, ultra-long-acting insulins, and autoimmune disease therapies. Founded by the team that developed the world's first clinical glucose-responsive insulin at SmartCells, Inc. (sold to Merck & Co.), Akston has partnered with Dechra Pharmaceuticals PLC (DPH) to commercialize once-a-week canine and feline insulin therapies in parallel to commercial launch of its Covid-19 vaccine. It owns and operates a GMP biologics manufacturing drug substance facility in addition to its research laboratory at its Beverly, Massachusetts location.

Primary Duties

- Manage operation of QC/GxP laboratory, including management of day-to-day quality control activities such as planning and coordination of release and in-process sample testing, stability sample testing, and pre-clinical and clinical sample testing
- Ensure that direct reports follow proper documentation practices, and that data entry and analyses are properly done.
- Manage the purchasing and expenses of the Quality Control group by maintaining a budget, and interacting with the Director, Quality Control and Assay Development to stay within those budgets.
- Manage the deliverables of the Quality Control group by maintaining a project schedule to align with company goals, directives and milestones set forth for the group.
- Perform independent review of quality control data, assay records, and study reports for accuracy and cGMP/GLP/ICH compliance
- Independently write and/or review analytical reports, deviation reports, change controls, and other quality documents
- Support Quality Control staff with respect to writing, updating, and reviewing protocols, SOPs and analytical reports to ensure they meet internal technical requirements, and GMP/ICH regulatory guidelines
- Assist in the management of outsourced in-process, release, and stability testing
- Oversee the maintenance of laboratory instruments to ensure proper working order and troubleshoot malfunctions when needed; this includes oversight of routine cleaning and maintenance, calibrations, repair, and IQ/OQ/PQ of equipment.
- Confer with other scientists to review and analyze scientific data, interpret test results, and compile results into assay or technical reports.

Other Responsibilities & Skills

- Knowledge of cGMP, GLP, FDA, EMA, and ICH guidelines.
- Independently understand the technical and quality aspects of quality control projects.
- Experience with a variety of analytical methods such as ELISA, qRT-PCR, HPLC, cIEF, and CE-SDS.
- Good organizational skills with the ability to adapt to changing priorities, to work both independently and within a team, to multi-task in a fast-paced and dynamic environment and to meet challenging timelines.
- Strong attention to detail.
- Strong communication and interpersonal skills.

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Qualifications

A bachelor's degree in Chemistry, Biology, Biomedical, Pharmaceutical Sciences or related field with 15+ years of work experience, a master's degree with 10+ years of work experience, or a PhD with 5+ years of work experience in the pharmaceutical or biotech industries required; GMP and/or GLP experience is required; Quality Control Laboratory experience strongly preferred.

Experience

The successful candidate shall**:**

- Have extensive experience in at least one of the following areas: management of quality control personnel and activities such as stability studies, release and in-process sample testing; writing technical reports, validation reports and SOPs; review of data and analytical reports for accuracy and GMP compliance.
- Have formal training and previous work experience in a cGMP or quality control laboratory.
- Have theoretical and hands on familiarity with a variety of analytical methods such as ELISA, qRT-PCR, HPLC, cIEF, and CE-SDS, preferably in a cGMP or QC environment.
- Demonstrate strong skills with common analytical programs (e.g., SoftMax Pro, Prism, etc.), Microsoft Word, Excel, and PowerPoint

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 Manager** 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 sylaja.murikipudi@akstonbio.com