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

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

Title Quality Control Data Review Manager

Primary Duties

- Perform independent review of quality control data, assay records, validation reports, and study reports for accuracy, scientific validity, and cGMP/GLP/ICH compliance
- Prepare Certificates of Testing and Certificates of Analysis for raw materials, Akston made materials, and in-process samples tested by Quality Control.
- Responsible for ensuring the maintenance of data integrity in the Quality Control laboratory
- 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 and release testing and results
- Confer with scientists to review and analyze scientific data, interpret test results, and compile results into assay or technical reports.

Other Responsibilities & Skills

- Theoretical and hands on familiarity with a variety of analytical methods such as ELISA, qRT-PCR, HPLC, cIEF, and CE-SDS.
- Knowledge of cGMP, GLP, and ICH guidelines
- Strong attention to detail
- Independently understand the technical and quality aspects of quality control projects
- 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 communication and interpersonal skills

Qualifications

A bachelor's degree in Chemistry, Biology, Biomedical, Pharmaceutical Sciences or related field with 12+ years of work experience, a master's degree with 8+ years of work experience, or a PhD with 3+ 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: review of data and analytical reports for accuracy and GMP compliance; writing technical reports, validation reports and SOPs; management of quality control activities such as stability studies, release and in-process sample testing.
- Have formal training and previous work experience in a cGMP or quality control

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- Experience in performing analytical assays in one or more of the following analytical areas, preferably in a cGMP or QC environment, a plus: ELISAs (e.g, host cell protein, anti-drug-antibody, etc.), qRT-PCR, HPLC (SEC, RP-HPLC, analytical Protein A, etc.), or microbiological assays.
- Be familiar with common analytical programs (e.g., ChemStation or Empower, SoftMax Pro, 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 Data Review 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