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**.

Title **Quality Control Associate**

Primary Duties

- Assist in the development and validation of analytical methods in support of COVID-19 vaccine development, Type-1 Diabetes therapeutic development, veterinary product development, and other projects as needed.
- Conduct in-process testing, release testing, and stability studies, of pharmaceutical products in a GMP environment in support of COVID-19 vaccine development, Type-1 Diabetes therapeutic development, veterinary product development or other projects as needed
- Assist with the receipt, quarantine, and release of raw materials and other controlled inventory, including Akston-made controlled materials.
- Participate in conduct of GLP or clinical in vivo study sample analysis in support of tox studies and clinical trials
- Write analytical method and instrument SOPs for use within the Quality Control lab
- Conduct environmental monitoring of GMP production spaces, including clean rooms and sterile hoods.
- Conduct bioburden testing of buffers and other solutions used in GMP manufacturing processes.
- Help maintain laboratory instruments to ensure proper working order and troubleshoot malfunctions when needed; this includes routine cleaning and maintenance, calibrations, and IQ/OQ/PQ of equipment.
- Support conduct of analysis of scientific data, interpreting test results, and compiling results into assay or technical reports.

Other Responsibilities & Skills

- Keep detailed records of data and appropriately document experimental procedures and results according to established guidelines
- Must be capable of multi-tasking, working both independently and within a team environment
- Communicate with outside vendors to learn new technologies and implement, where applicable, into Akston's process.
- Strong communication and interpersonal skills.
- Ability to develop solutions to complex problems and establish processes to continuously improve and streamline existing procedures
- 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

Qualifications A bachelor's degree in Chemistry, Biology, Biomedical, Pharmaceutical Sciences or related field with 3+ years of work experience in analytical laboratories in the pharmaceutical or biotech industries required, or a masters with 1 – 3 years of

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pharmaceutical industry work experience; Quality Control Laboratory experience in support of GMP/GLP preferred.

Experience

The successful candidate shall**:**

- Have hands on experience with analytical assays in one or more of the following analytical areas, preferably in a cGMP or QC environment: ELISAs (e.g., host cell protein, anti-drug-antibody, etc.), qRT-PCR, or microbiological assays. Experience with other analytical methods (e.g., endotoxin testing, SDS-PAGE, etc.) a plus. Proven ability to troubleshoot and solve problems with assays both during development and routine work
- Have some experience in at least one of the following areas: writing technical reports, validation reports and SOPs; conducting release and stability testing for pharmaceutical products; environmental monitoring; working in an aseptic environment (e.g., clean room or sterile hood); and performing analytical instrument IQ/OQ/PQ and calibration.
- Formal training and previous work experience in a cGMP or quality control laboratory highly desirable
- Demonstrate familiarity with common analytical programs (e.g. GraphPad Prism, 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 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