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 Senior Scientist I**.

Title **Quality Control Senior Scientist I**

Primary Duties

- In-process testing, release testing, and stability studies, of pharmaceutical products in a GMP environment in support of veterinary product development, COVID-19 vaccine development, Type-1 Diabetes therapeutic development, or other projects as needed.
- GLP or clinical in vivo study sample analysis in support of tox studies and clinical trials.
- Analytical method validation in support of COVID-19 vaccine development, Type-1 Diabetes therapeutic development, veterinary product development, and other projects as needed.
- Act as SME providing training of other QC personnel within the department
- Generate and/or support deviations and change controls
- Conduct OOS and laboratory investigations,
- Troubleshoot equipment and analytical testing methods
- Participate in development of analytical methods in support of COVID-19 vaccine development, Type-1 Diabetes therapeutic development, veterinary product development, and other projects as needed.
- Confer with other scientists to review and analyze scientific data, interpret test results, and compile results into assay or technical reports.
- Assist with environmental monitoring, including plating and analysis of settle plates and bioburden plates, and air sampling of manufacturing areas.
- Maintain laboratory instruments to ensure proper working order and troubleshoot malfunctions when needed; this includes routine cleaning and maintenance, calibration, and IQ/OQ/PQ of equipment.

Other Responsibilities & Skills

- Keep detailed records of data and appropriately document experimental procedures and results according to established guidelines
- 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
- Must be capable of working both independently and within a team environment
- Ability to help develop solutions to complex problems and establish processes to continuously improve and streamline existing procedures
- Strong communication and interpersonal skills.

Qualifications A master's degree in Chemistry, Biology, Biomedical, Pharmaceutical Sciences or related field with 14+ years of work experience in analytical laboratories in the pharmaceutical or biotech industries required, or a PhD with 8+ years of pharmaceutical industry work experience; cGMP and/or GLP Laboratory experience strongly preferred.

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Experience

The successful candidate shall**:**

- Demonstrate a strong proficiency in conducting analytical assays in one or more of the following analytical areas, preferably in a cGMP or QC environment: ELISAs (e.g., potency, host cell protein, anti-drug-antibody, etc.), qRT-PCR, cell-based assays, or HPLC (SEC-HPLC, Analytical Protein A, etc.). Experience with other analytical methods (e.g., endotoxin testing, microbiological testing, raw materials testing, etc.) a plus.
- Have the proven ability to troubleshoot and solve problems with assays.
- Have extensive experience in several of the following areas: writing technical reports, validation reports and SOPs; conducting release testing for pharmaceutical products; stability studies; OOS and other laboratory investigations; and performing analytical instrument IQ/OQ/PQ and calibration.
- Formal training and previous work experience in a cGMP or GLP laboratory highly desirable
- 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 Corporation invents, develops, and manufactures breakthrough protein therapeutics for Companion Animal Health. We leverage our novel Ambifect™ Fc-fusion platform to develop and manufacture new classes of therapeutics. Additionally, Akston serves as a Contract Manufacturing Organization (CMO) for other Animal Health companies through production and manufacturing facilities that are dedicated to Animal Health. Our facilities, along with our research and process development laboratories, are located in Beverly, Massachusetts. For more information, see www.akstonbio.com.

Contact

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