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 Scientist I**

Title **Quality Control Scientist I, Environmental Monitoring and Microbiology**

Primary Duties

- Responsible for oversight of Environmental Monitoring (EM) performed by contract testing laboratory (CTL) using viable air sampling and surface organism plating per USP<1116>. Review all monthly EM reports and investigate any action and/or alert level results.
- Trend CTL EM data on a regular basis, and create monthly EM trending summaries and/or other trending reports.
- Serve as an subject matter expert on interdepartmental EM group to assist with defining and assessing action or alert limits, long-term EM strategy, and investigating aberrant results within cleanroom that exceed current action or alert limits.
- Communicate inter-departmentally and with outside EM CTL to resolve compliance and technical issues.
- Verify or perform air monitoring using METOne particle counters and environmental monitoring (e.g., settle plates).
- Responsible for coordination and scheduling of personnel for air monitoring performed in Akston cleanroom. Assist with coordinating additional resources where necessary.
- Responsible for routine and non-routine bioburden testing events, including scheduling additional resources as needed.
- Accurately document bioburden results from Akston or external CTLs when needed. Accurately follow applicable written procedures.
- Write, revise and review material specifications, change controls, deviations, and SOPs related to bioburden and environmental monitoring.
- Evaluate current bioburden and EM programs to broaden scope and improve alignment with USP and EP requirements.

Other Responsibilities & Skills

- Evaluate bioburden testing program for validation requirements, and setup and/or perform studies to validate test samples (e.g., mitigation of interference of buffer components, new methodology etc.)
- 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.
- Must be extremely detail-oriented, with solid attention to documentation detail in compliance with GMPs.
- Capable of executing cGMP training, and working in compliance with cGMPs, effectively demonstrating an understanding of cGMP’s relevant to role.

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- 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.
- 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., endotoxin testing, endotoxin validation) if needed.

Qualifications

- A minimum of a bachelor's degree in Chemistry, Microbiology, Biology, Biomedical, Pharmaceutical Sciences or related field, preferably with 7 to 10 years of work experience in a GMP environment in the pharmaceutical or biotech industries, with a focus on Microbial and/or EM Laboratory experience. Equivalent combination of education, training and relevant work experience may be considered. Candidates with Master's Degree in relevant Scientific discipline with 3 to 5 years of experience may be considered.
- Laboratory experience in support of cGMP/GLP is a plus.
- Must be a self-starter, able to work with minimal supervision, and able to take initiative on microbiological and EM projects.
- Display strong interpersonal, oral and written communication skills, ability to effectively communicate with peers and area management.

Experience The successful candidate shall**:**

- Experience with Microbiological or EM testing is required.
- Formal training and previous work experience in a cGMP or quality control laboratory, including experience with bioburden and EM testing, highly desirable.
- Some experience in at least one of the following areas: writing technical reports, validation reports and SOPs; bioburden validation.
- Demonstrate familiarity with Microsoft Word, Excel, and PowerPoint
- 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 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.

Akston has an immediate opening for a **Quality Control Scientist** 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