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.
  + 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 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 Scientist** position for the company located in Beverly, MA. For more information, see [www.akstonbio.com.](http://www.akstonbio.com/)

**Contact** Candidates should send CV and cover letter to [careers@akstonbio.com](mailto:careers@akstonbio.com) or [sylaja.murikipudi@akstonbio.com](mailto:sylaja.murikipudi@akstonbio.com)