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 Assurance/ Sr. Quality Assurance Manager – QA Operations**

Title **Quality Assurance/ Sr. Quality Assurance Manager – QA Operations**

Primary Duties

- Supervise and manage direct reports and interns that are assigned to the position. This includes overseeing day to day activities and implementation of tasks by QA department staff, organizing and assigning tasks, monitoring progress, giving guidance as needed, and ensuring timely project deliverables to manufacturing and quality control units.
- Manage and implement **Quality Assurance operation** workflows: (1) equipment quality management (calibrations, PM and IQ/OQ/PQ), (2) SOP review, approval and renewals, (3) employee training and training records, (4) review and approval of QC/analytical/validation data and reports, (5) QA review of GMP records and logs, (6) document management and archival, (7) review and approval of controlled material records, (8) QA review and control of GMP facility records, (9) review of Temp/RH and EM records and reports, and (10) implementation of eQMS (Master Control).
- Assist and support **Quality Assurance compliance** workflows as needed: (1) deviation management, (2) change control management, (3) risk/impact assessment, (4) implementation of CAPA, (5) investigation of quality events/incidents, (6) Out of Specification investigations, (7) internal audits and inspections, (8) drug substance/drug product inventory and label control, (9) MBR/PBR issuance and control, and (10) PBR reviews and close out for batch release.
- Assist implementation of quality policies and procedures to ensure established quality standards in regulated GMP manufacturing units and QC/GLP laboratories.
- Assist monitoring and identifying non-conformances and quality problems in GxP units and propose corrective actions and improvement plans.

Other Responsibilities & Skills

- Strong attention to detail
- 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 or master's degree in life sciences, preferably majoring in Biology, Biomedical, Pharmaceutical Sciences or relevant field and at least **5 years of experience in Quality Assurance** in support of GMP/GxP and **2 years of experience in managing direct reports.**

Experience

The successful candidate shall**:**

- Demonstrate proficiency in quality systems and QA activities in a regulated pharmaceutical environment to ensure GxP compliance
- Possess a working knowledge of tools, methods, and concepts of quality assurance and of

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relevant regulatory standards

- Have good knowledge of FDA, EMEA and other applicable industry and quality regulations

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 using our novel fusion protein platform. We have built a diverse pipeline of therapeutic candidate including a clinical stage COVID-19 vaccine, ultra-long-acting insulins and autoimmune disease therapies. We own and operate a GMP biologics manufacturing drug substance facility in addition to its research laboratory at its Beverly, Massachusetts location.

Akston has an immediate opening for a **Quality Assurance/ Sr. Quality Assurance Manager** position in Beverly, MA. For more information, see www.akstonbio.com.

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