AKSTON BIOSCIENCES

Akston Biosciences Corp.
100 Cummings Ctr., Ste. 454C
Beverly, Massachusetts 01915

Office: 978-969-3381
Fax: 978-522-8499

Akston Biosciences Corporation
Manufacturing Quality Engineer II/III
Position Description

Akston Biosciences Summary

Akston Biosciences Corporation leverages its novel fusion protein platform to develop and manufacture new classes of biologics, including vaccines, ultra-long-acting insulins, and autoimmune disease therapies. Founded by the team that developed the world's first clinical glucose-responsive insulin at SmartCells, Inc. (sold to Merck & Co.), Akston has partnered with Dechra Pharmaceuticals PLC (DPH) to commercialize once-a-week canine and feline insulin therapies in parallel to commercial launch of its Covid-19 vaccine. It owns and operates a GMP biologics manufacturing drug substance facility in addition to its research laboratory at its Beverly, Massachusetts location.

Position Responsibilities, Skills and Requirements

Reporting

- Reports to VP, Manufacturing and Product R&D

Manufacturing and Process-related

- Perform independent review of master batch records and executed production batch records.
- Assist manufacturing staff with respect to reviewing and implementing change controls and updating SOPs.
- Assist manufacturing management in developing and implementing within-manufacturing trainings.
- Develop manufacturing protocols, inspection instructions and work instructions to support manufacturing operations.
- Determine quality improvement parameters by identifying statistical methods relevant to manufacturing processes.
- Establish statistical confidence by identifying sample size and acceptable error, and determining levels of confidence.
- Analyze data by completing hypothesis, normal distribution, and process capability analysis tests.
- Prepare reports by collecting, analyzing, and summarizing data; and making recommendations.
- Maintain professional and technical knowledge by attending educational workshops, reviewing professional publications, establishing personal networks, benchmarking state-of-the-art practices, participating in professional societies, and maintaining ASQ-certified quality engineer qualification.
- Ensure products adhere to company and industry quality standards.
- Brainstorms ideas to create solutions for identified problems.

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Quality Management System (QMS)-related

- Independently write standard operating procedures (SOPs), deviation reports, change controls, quality memos.
- Take the lead on seeing through manufacturing-related investigations to completion, including preparation of investigation reports.
- Work with Akston Manufacturing and Quality Assurance staff to execute change controls, SOPs revisions, memos, training and CAPAs.
- Act as the liaison between Manufacturing and Quality Assurance with respect to developing new workflows as the company transitions to using an electronic quality management system (eQMS).
- Preparation of inspection reports.
- Coordination and performance of internal process/product audits.

Education, required skills and experience

- A bachelor's degree in engineering or equivalent discipline is required.
- The candidate must have relevant work experience, including 2-5 years in a GMP manufacturing environment with prior knowledge and experience of quality systems.
- Root cause analysis experience preferred.
- Above average math skills is required (sound knowledge in statistics).
- Exhibit very strong to excellent written and verbal communication, analytical, and problem-solving skills.
- Communicate effectively with all levels of staff and management, both internal and external.
- Independently understand the technical and quality aspects of manufacturing projects.
- Capacity to work independently from general supervision (must be self-motivated once given direction and embrace the entrepreneurial spirit of the company).
- Ability to perform multiple tasks and obtain results working within strict time frames
- Strong attention to detail.
- Proficient in MS Office software including Word, Excel, Outlook, and PowerPoint, as well as statistical software tools like SAS, JMP and Graphpad Prism.
- Ability to read and interpret assembly and component drawings and engineering specifications.

Education

- Candidates are required to have a bachelor's or master's degree in chemical engineering, bioprocess engineering, or related field and a minimum of three years of industry experience.

Other

- Must live within commuting distance of Beverly, MA. No company-paid relocations.

Interested candidates should send a cover letter and CV to careers@akstonbio.com