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

Office: 978-969-3381
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Senior Engineer I, Downstream Process Development

Company

Akston is a biotech company built for pets. Using our proprietary Ambifect® Fc-fusion protein platform, we develop immuno-enhancing and targeted protein treatments that aim to reduce treatment frequency while enhancing efficacy. Backed by a vertically integrated structure and state-of-the-art biologics facility, we accelerate development from discovery to commercial manufacturing – ensuring innovation reaches veterinarians and the pets we love, faster and more efficiently. Learn more at www.akstonbio.com.

Position Summary

The Downstream Process Development group at Akston encompasses lab-scale development, pilot-scale operations, and at-scale Manufacturing Science and Technology (MSAT) support. This position is primarily responsible for advancement of Akston's therapeutic pipeline through the development of robust, cost-effective, and scalable processes for new and existing products through all drug development stages. The individual will be involved in hands-on non-GMP lab work as well as providing GMP operational support. Cross-functional collaboration with all other groups in the company, including R&D, Pharmacology, Upstream Process Development, Manufacturing, QA, and QC, is an essential part of this role.

Primary Duties

Process Development:

- Act as the subject matter expert (SME) for various mAb and Fc-fusion protein purification technologies and practices, including but not limited to chromatography, column packing, tangential flow filtration (TFF), and viral filtration
- Design small-scale process optimization experiments using Design of Experiment (DoE) and Quality by Design (QbD) principles, with a focus on impurity clearance and characterization of Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs)
- Perform lab-scale experiments as needed and generate non-GMP drug substance/product to support in-vivo and clinical trial material supply requirements
- Analyze analytical assay results, including ELISA, HPLC, CE-SDS, cIEF, peptide mapping, glycan mapping, spectrophotometry, and endotoxin content
- Lead project planning and guide CMC strategies for long-term program success
- Participate in cross-functional teams to evaluate technical risk and impact of decisions across CMC
- Facilitate management of key external vendors, CDMOs, and CTOs
- Train, mentor, and coordinate activities of junior staff members
- Author technical reports and assist in the preparation of regulatory documents

Manufacturing Support:

- Assist with Downstream GMP manufacturing operations to purify up to 1000L bioreactor harvests
- Author SOPs, batch records, protocols, change controls, CAPAs, risk assessments, impact assessments, and other GMP Quality documents
- Provide technical support for process incident resolution, including deviation and investigation support

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- Lead technology transfer of new processes to ensure smooth transition from process development to GMP manufacturing
- Prospectively project manufacturing material usage, equipment needs, and scheduling to ensure the timelines are met
- Support equipment procurement, installation, qualification (IQ/OQ/PQ), validation, and preventative maintenance activities
- Drive continuous improvement through the adoption of innovative solutions to enhance efficiency, data analytics, and operational performance

Other Responsibilities & Skills

- Demonstrate solid understanding and use of engineering principles and practices to solve a range of complex problems in creative and practical ways
- Exercise independent judgment and decision making with minimal supervision and direction, while multitasking between multiple projects to meet challenging deadlines
- Exhibit strong verbal and written communication skills, attention to detail, and time management skills
- Stay up to date with state-of-the-art purification technologies and actively seek opportunities for continuous improvement
- Limited travel may be required (~5%)
- Ability to lift up to 25 lbs.

Qualifications

- Bachelor's degree in engineering, chemistry, biology, biomedicine, pharmacy, or other related pharmaceutical science and 8+ years of work experience
- Master's degree in engineering, chemistry, biology, biomedicine, pharmacy, or other related pharmaceutical science and 6+ years of work experience
- Ph.D. in engineering, chemistry, biology, biomedicine, pharmacy, or other related pharmaceutical science and 3 – 5 years of work experience

Experience

The successful candidate shall demonstrate**:**

- Substantial experience in R&D/PD laboratory and GMP manufacturing environments
- Experience in team leadership, project management, root cause analysis principles, and process improvement principles such as LEAN or Six Sigma/DMAIC
- Proficiency with Microsoft Word, Excel, and PowerPoint
- Familiarity with analytical and statistical processing software, such as JMP
- Experience with process validation is preferred

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Compensation

Title and pay commensurate with skills and experience, eligibility for company benefit plans.

Other

This is an on-site, non-remote position. Must live within commuting distance of Beverly, MA.

Contact

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

For more information, see www.akstonbio.com.