AKSTON BIOSCIENCES

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

Office: 978-969-3381
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Position Openings – Upstream Process Development

Title Process Development, Senior Engineer I

Reporting Reports to Manager, Upstream Process Development

Company Akston Biosciences is developing novel biologic therapeutics including novel Covid-19 vaccines, preventative treatments for human autoimmune diseases and long-acting insulins for companion animal diabetes. Focused on innovation, our employees thrive in an environment in which individuals can excel while building on their diverse strengths. Within Akston Biosciences Corporation, Upstream Process Development (USP) department is responsible for the development, characterization, scale-up, and transfer of cell culture processes for early and late stage clinical and commercial manufacturing of therapeutic proteins. In addition, the department provides technical expertise and support for improving the performance of commercial manufacturing processes.

Qualifications A bachelor's degree with 8+ years of experience, master's degree with 6+ years of experience or Ph.D with 3+ years of experience in Chemical or Biological Science, Chemical Engineering, Biomedical Engineering or equivalent in the biotech manufacturing sector is required.

Experience The candidate shall:

Responsibilities – Process Development

- Demonstrate expertise with the following techniques and equipment: mammalian cell culture with aseptic technique, cell culture without use of antibiotics, various cell cultureware and techniques (shake flasks, spinner flasks in laminar flow hoods and incubator-shakers).
- Demonstrate mastery of cell seed train processing, and the setup and execution of 2L-1000L single-use bioreactor runs, including bioreactor software and controls (experience with Sartorius bioreactors, MilliporeSigma bioreactors, and Cytiva bioreactors including Wave bioreactors is plus), and depth filtration.
- Be chiefly responsible for optimization experiments with CHO cell lines, including the design of experiments for the optimization of media for enhanced product titer.
- Identify seed train, media, bioreactor, and harvest variables most impact on product critical quality attributes (CQAs), and assist in defining critical process parameters (CPPs) to produce consistent product with acceptable quality attributes with minimal lot-to-lot variability.
- Demonstrate familiarity with QbD (Quality by Design) and use of Ambr15/Ambr250 systems to identify critical quality attributes (CQAs) through outsourced upstream development projects.
- Ensure that outsourced upstream process development project Ambr15/Ambr250 optimized upstream process parameters are verified through internal Akston shake flask and bioreactor studies.
- Review CDMO contracts and statements of work, and assist with CDMO projects to ensure their successful completion

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- Demonstrate strong skills with common software programs such as Microsoft Word, Excel, and PowerPoint; and familiarity with data analysis software such as GraphPad Prism, JMP, and/or SAS.
- Interface with other upstream team group members to assist in analyzing data and providing insights to their experiments.
- Demonstrate strong technical writing skills and be chiefly responsible for writing process development reports and reviewing and editing process development reports from other upstream PD team members.
- Demonstrate good adherence to established SOPs, batch records, and training within Akston's quality system.
- Be able to troubleshoot and make moderate repairs to peristaltic pumps, blood gas analyzer, cell counter, culture electrolyte and metabolite determination, and HPLC for determination of protein titer and quality of product.
- Exhibit strong familiarity with the safety, maintenance, cleaning, and operational aspects of the above equipment and processes.

Responsibilities – GMP Manufacturing

- Support upstream GMP manufacturing efforts, including seed train, bioreactor runs and depth filtration at 10L to 1000L bioreactor scales.
- Support GMP manufacturing efforts by writing equipment SOPs, Master Batch Record (MBRs) and participating in equipment installation qualifications (IQ), operational qualifications (OQ) and performance qualifications (PQ).

Responsibilities – Other

- Maintain detailed records of data, including a well-organized laboratory notebook, document experimental procedures and results according to established guidelines, and synthesize key learnings into well-written process development reports.
- Work both independently and within a team environment, while multitasking between projects.
- Demonstrate ability to understand and interpret data and its practical application.
- Communicate with outside vendors to learn and implement new technologies, where applicable, into the company's processes.
- Assist in ordering of laboratory/facility supplies.

Compensation Pay commensurate with skills/experience, stock option plan, and company benefits plan, including retirement savings plan and company medical plan.

Other Must live within a 30-minute commuting distance of Beverly, MA.

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