AKSTON BIOSCIENCES

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

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

Position Openings – Upstream Process Development

Title Process Development, 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. We offer exciting development opportunities for employees to learn from industry professionals. 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 or master's degree in Chemical or Biological Science, Chemical Engineering, Biomedical Engineering or equivalent and 0-3 years of work experience in the biotech manufacturing sector is required.

Experience The candidate shall demonstrate experience or familiarity with, or willingness to train on the following techniques and equipment:

- Aseptic technique (cell culture without use of antibiotic).
- Cell culture experiments at various scales from shake flasks, spinner flasks, and bench-top bioreactors.
- Setting up and execution of 2L-200L bioreactors, including bioreactor software and controls (experience with MilliporeSigma and Cytiva bioreactors, including Cytiva Wave bioreactor is plus).
- Daily bioreactor sampling and data entry.
- Cell seed train calculations.
- Blood gas analyzer (BGA), cell counter (Vi-Cell XR), culture electrolyte and metabolite determination (Nova Bioprofile Flex/Flex2).
- HPLC for determination of protein titer and quality of product is plus.
- Safety, maintenance, cleaning, and operational aspects of upstream process development equipment and processes.
- CHO cell lines, design of experiments for the optimization of media for enhanced product titer, Ambr 15/Ambr 250 equipment, and/or experience with single-use disposable upstream production at multigram scales is preferred.
- Common software programs such as Microsoft Word, Excel, and PowerPoint; and data analysis software such as GraphPad Prism, JMP, and/or SAS.

For more information, visit Akston Biosciences at www.akstonbio.com

V06Oct2022

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Responsibilities – R&D / Process Development

- Implement protein titer optimization experiments at small scales in shake flasks to support scaleup and process development optimization of lead therapeutic products.
- Perform small scale 2L/10L/50L bioreactor runs to confirm shake flask data from optimization experiments.
- Identify which seed train, media, bioreactor, and harvest variables most impact on product quality attributes, and assist in refining process to produce consistent product with acceptable quality attributes with minimal lot-to-lot variability.
- Create seed train methods and protocols for use by other company upstream staff in support of process scaleup and implementation into manufacturing.
- Assist other upstream staff in implementing cell line development efforts.
- Assist in scaling up the current and optimized process to 200L bioreactor scales.
- Assist in writing draft upstream SOPs.

Responsibilities – GMP Manufacturing

- As needed, support upstream GMP manufacturing efforts, including seed train, bioreactor runs and depth filtration at 50L to 1000L bioreactor scales.
- Support GMP manufacturing efforts by writing equipment SOPs and participating in equipment installation qualifications (IQ) and operational qualifications (OQ).

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.
- Troubleshoot and maintain key equipment.

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