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, Engineer I/II

Reporting Reports to Vice President, Manufacturing and Product Research and 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. The biotechnology firm is currently recruiting to join its Process Development team located in Beverly, MA.

Qualifications A bachelor's degree or master's degree in Engineering, Chemistry, Biology, Molecular Biology, Immunology, Pharmaceutical Sciences, or related field and >3 years of work experience in the biotech manufacturing sector is required.

Experience The candidate shall**:**

Process Development

- Demonstrate experience with the following techniques and equipment: mammalian cell culture with aseptic technique, cell culture without use of antibiotics, familiarity with various cell cultureware and techniques (shake flasks, spinner flasks in laminar flow hoods and incubator-shakers), cell seed train calculations, setup and execution of 2L-50L bioreactor runs, including bioreactor software and controls (experience with Sartorius and GE bioreactors, including Wave bioreactors is a plus), depth filtration, 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.
- Experience with 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.
- 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.

Quality Control

- Demonstrate experience with ELISA, and other 96-well assay formats.
- Demonstrate competency in running potency and other cell-based assays, including culturing primary cells without the use of antibiotics.
- Demonstrate good adherence to established SOPs, batch records, and training within Akston's quality system.

Responsibilities – GMP Manufacturing

- As needed, support upstream GMP manufacturing efforts, including seed train, bioreactor runs and depth filtration at 50L to 1000L bioreactor scales.

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

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- Support GMP manufacturing efforts by writing equipment SOPs and participating in equipment installation qualifications (IQ) and operational qualifications (OQ).

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 – 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, company retirement savings plan, and eligibility for company medical plan.

Other Must live within a 40 minute commuting distance of Beverly, MA.

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