AKSTON BIOSCIENCES

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

Office: 978-969-338
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e-mail: info@akstonbio.cor

Title

- Senior Associate I – Manufacturing Operations

Reporting

- Reports to the Director of Manufacturing Operations and/or Supervisor of Manufacturing Operations

Company

- Akston Biosciences is developing novel biologic therapeutics for the treatment and prevention of human autoimmune diseases and companion animal diabetes. The biotechnology firm is currently recruiting a Senior Associate I – Manufacturing Operations to join its dynamic and fast-paced GMP Manufacturing Operations team located in Beverly, MA.

Duties

Primary Duty

Performs routine manufacturing operations for the production of clinical and/or commercial products. Operates production equipment according to Standard Operating Procedures (SOPs). Performs manufacturing activities of full scope, including, but not limited to work in Cell Culture, Purification, Solution & Equipment Preparation areas. Will be required to assist with generating and editing of manufacturing SOPs. Maintain records and clean room environment to comply with regulatory requirements, GMPs, and SOPs.

Other Duties

- Participate in cross-functional teams (Facilities, Quality Assurance, Quality Control, etc.) to assist with daily operations within the GMP Manufacturing facility
- Ensure that the GMP Manufacturing cleanroom facility is ready for all GMP manufacturing related activities by always being in a state of "audit-ready"
- Assist the Manufacturing Operations team in creating, writing, and implementing key facility and manufacturing operational SOPs
- Where necessary, assist with equipment installation and IQ, OQ, and PQ, and equipment calibration and preventative maintenance activities
- Documentation and computer skills
- Operate manufacturing equipment in strict accordance to MBRs and SOPs to achieve desired outcomes

Qualifications

- High school diploma/GED and greater than 5 years of GMP related manufacturing experience
- Demonstrate experience and understanding of biologics manufacturing processes and associated manufacturing equipment
- Experience with working in a team of manufacturing technicians in a commercial GMP manufacturing setting

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Requirements The individual shall:

- Demonstrate strong knowledge of GMP behaviors in a GMP regulated cleanroom environment by complying with GMP regulated SOPs and MBRs
- Take and follow direction during GMP manufacturing operations
- Display effective communication skills, including strong oral and written abilities that can be brought to bear on interfacing with the manufacturing team members, and company management
- Demonstrate the ability to lift, pull or push materials requiring 50 lbs. of force
- Demonstrate the ability to stand for extended periods of time
- Be reliable and work independently when required

Other

- Will work holidays and overtime as required
- May be required to adjust work schedule to meet production demands
- Must live within commuting distance of Beverly, MA

Compensation

- Pay commensurate with skills/experience