

**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

**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

Candidates should send CV and cover letter to [careers@akstonbio.com](mailto:careers@akstonbio.com)