

Office: 978-969-3381 Fax: 978-522-8499 Beverly, Massachusetts 01915 e-mail: info@akstonbio.com

Position Description

Title

Maintenance Mechanic II – GMP Facilities

Reporting

Reports to the Director of Manufacturing Operations

Company

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

Duties

Primary Duties

Ensure the efficient maintenance and reliable operation of the process and utility equipment needed to support a GMP manufacturing facility including supporting laboratories

Secondary Duties

Supervise services that support GMP operations including, but not limited to, cleaning contractors, gowning vendors, gas supply vendors, utility providers, etc.

Qualifications

- High school diploma or equivalent plus 3-5 years of related industry experience or relevant Associates Degree in Life Science/Engineering field with 2-4 years of cGMP plant operations experience
- Certification(s) preferred

Requirements The individual shall:

- Possess prior work experience in a GMP, biotechnology and/or FDA regulated environment
- Comprehend and apply Standard Operating Procedures (SOPs) to follow cGMP guidelines to ensure compliance to regulatory agencies
- Demonstrate experience in repair, operation, and troubleshooting of electro-mechanical process equipment and utility systems including, but not limited to, air handlers, generators, humidifiers, etc.
- Exhibit familiarity with controls systems, PLC's, SCADA and BMS systems preferred but not required
- Demonstrate technical writing skills including, but not limited to, SOPs and Maintenance procedures
- Demonstrate the ability to learn and read complex mechanical drawings
- Be able to lift, pull or push equipment requiring 50 pounds of force
- Be both a "hands on" worker and a supervisor of subordinates and contractors



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Responsibilities The individual will:

- Be responsible for the operation and maintenance of plant systems, utilities and equipment in a stateof-the-art GMP manufacturing facility as well as supporting laboratories
- Perform and supervise the execution of routine preventative maintenance and non-routine work orders throughout the facility
- Comply with GMP requirements to include detailed documentation of work performed in both electronic and written forms and maintain those records
- Direct and organize any vendors and consultants that support the operation of the manufacturing facility and supporting units

Other

- Required to carry a mobile phone at all times and be on call as required to support operations and participate in off-hour emergency coverage as needed
- Must be able to climb a ladder, reach, bend and lift loads up to 50 pounds
- Must live within commuting distance of Beverly, MA

Compensation

Pay commensurate with skills/experience