



<https://www.biolink360.com/job/engineering-controls-manager/>

## Engineering Controls Manager-Cell Therapy

### Description

**Title:** Engineering Controls Manager-Cell Therapy

**Location:** Lowell, MA

**Reports to:** Site Operations Director

**Type of role:** Hybrid

**Salary:** 120-180K

Our client is a leader in the cell and gene therapy space that is revolutionizing medicine and looking to add an accomplished and dynamic Engineering Controls leader. The person hired into this role will be helping with the expansion of company's manufacturing capabilities.

The Engineering Controls Manager will oversee operations through technical assistance for the manufacturing and process automation systems. The controls engineering team provides a technical resource to operations customers to ensure that instrumentation and automation systems are designed and operating to meet production needs.

### Responsibilities

- Management of a team of controls engineers and contractors (as needed) to support ongoing operations, continuous improvements and projects.
- Planning and execution of plant projects involving complex equipment changes and significant process improvements. May be involved in capital projects or initiation of CARs
- Owns and executes completion of CAPA actions
- Conduct troubleshooting and technical/root cause analyses on manufacturing equipment and processes automation systems including PI data analyses, review/troubleshooting code, etc. both during normal business hours and as part of an on-call rotation.
- Oversight of tech transfers, which are managed by delegates (controls leads).

### Qualifications

- Minimum Bachelor of Science degree
- Minimum of 8 years of Quality Control experience in the biologics/cell/gene therapy industry
- Minimum of 3 years management experience in Quality Control or Quality Assurance
- Excellent knowledge of cGMP guidelines, USP/NF, 21 CFR Parts 210 and 211, 21 CFR Part 11, and other regulatory standards
- Technical writing experience in a similar role in the biologics or pharmaceutical industry
- Experience in aseptic processing and/or mammalian cell culture production

### Hiring organization

BioLink 360

### Employment Type

Full-time

### Industry

Pharma/Biotech

### Job Location

Lowell, MA

### Base Salary

\$ 130,000 - \$ 180,000

### Date posted

October 24, 2024