



**Genesee**

BIOMEDICAL, INC.

*Design beyond standard.*

## Quality Assurance Manager:

### Job description

**Reports To:** Chairman of the Board, CEO & President

**Minimum Qualifications:** BS degree in related field. Regulatory experience in the Medical Device Field.

**Primary Objectives:**

The primary objective of the Quality Assurance Manager is to keep the company in compliance with the stated Quality Policy, FDA Quality Systems Regulations, ISO 13485 UK and European Medical Directive MDR; while participating as a contributing member of the company's management team, with the ultimate goal of enhancing the company's productivity and profitability.

**Quality Assurance Manager Job Duties:**

Position is hands on.

The Quality Assurance Manager is responsible for ensuring adherence to Quality Systems Regulations, compliance with FDA regulations, custody of the Master Document Files, inspection of materials, in-process and final products, customer complaints, internal audits, coordination of the Management Review Process.

To be Genesee BioMedical, Inc.'s Management Representative that has the responsibility and authority that includes:

1. ensuring that processes needed for the quality management system are documented.
2. reporting to top management on the effectiveness of the quality management system and any need for improvement;
3. ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

Quality Assurance Manager's goals are:

- 1). Ensure that the company is following the procedures established in its Standard Operating Procedures with regard to receiving, engineering, manufacturing, equipment calibration, sterility tests and internal external audits.
- 2). All products shipped by Genesee BioMedical, Inc. meet Genesee's Certificate of Conformance.
- 3). That the database of LAL, Bioburden and Sterilization is kept current.
- 4). Equipment Calibration and clean room/environment is conducted as required.
- 5). Arrange and aid in the conduct of Internal & External Audits.

Job Type: Full-time

Benefits:

- 401(k)
- Dental insurance
- Health insurance
- Life insurance
- Paid time off
- Vision insurance



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**Schedule:**

- 8 hour shift
- Monday to Friday

**Ability to commute/relocate:**

- Denver, CO 80223: Reliably commute or planning to relocate before starting work (Required)

**Education:**

- Bachelor's (Required)

**Experience:**

- ISO 13485: 2 years (Required)