# Mill Creek Life Sciences

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| Job Title: Quality Manager | Job Code: |
| Department: | Job Grade: |
| Revision Date: | Fair Labor Standards Act (FLSA): |

**Company Overview**

Mill Creek Life Sciences, LLC (MCLS) operates in Rochester, Minnesota and seeks to develop new cellular technologies and regenerative medicine therapies. Through our collaboration with research institutions such as the Mayo Clinic, we develop novel and high-fidelity solutions to issues in both clinical practice and research. Our technology extracts powerful growth factors, which stimulate cell growth and wound repair, from human blood products.

**Position Overview**

Quality Manager is responsible for leading the activities associated with maintaining the Quality management system at Mill Creek Life Sciences. Ensure products manufactured by Mill Creek are safe, effective and comply with all applicable customer and Regulatory requirements. The Quality Manager is directly responsible for implementation of quality systems and initiatives related to production and release of Mill Creek products.

**Essential Job Functions**

- Responsible for all aspects of company Quality Assurance in compliance with Regulatory standards
- Helps to develop and maintain a culture in which quality production is top priority and a spirit of continuous improvement is fostered
- Leads customer and regulatory audits
- Directs work priorities and activities for Quality Technician
- Participate in the development of the new products and processes, issue resolutions and design review participation.
- Identifies and manages continuous improvement projects with the objective of achieving quality, reliability and cost improvements.
- Performs batch review and release for all production lots
- Manages equipment maintenance schedule and alerts appropriate personnel of upcoming maintenance assignments
- Performs qualification of new suppliers
- Perform duties of Document Manager and Training Manager utilizing cloud-based software

**Non-essential Job Functions**

- Adheres to high standard of personal and professional conduct
- Maintains confidentiality of sensitive oral, paper-based, and electronic information
- Complies with MCLS defined policies, processes, and procedures in the conduct of routine activities
- Maintains competency in FDA Good Manufacturing Practices
- Shares knowledge and information to assist in education and training MCLS staff
- Maintains and enhances profession/competency skills

**Qualifications**

- Thorough knowledge of applicable procedures, specifications, regulations and standards.
- Familiarity with Cloud-Based document control systems.
- Strong analytical and problem-solving skills.
- Ability to manage/supervise a team of employees.
- Good communication and leadership skills.
- Good interpersonal/communication/influencing/negotiation skills.
- Good project management skills.

**Requirements**

- Minimum B.S. degree in science or Engineering
- 5+ years previous experience with FDA Good Manufacturing Practices (GMP) for product manufacturing and facility/environmental control procedures.
- High attention to detail
- Must be capable of working in a clean room environment in clean room attire
- Must possess good communication skills and be able to work closely with others
- Previous FDA GMP experience preferred or able to complete course work within 1 month

**Other Skills/Abilities**

- Good personal hygiene

**How To Apply**

- To apply please send a resume and cover letter to info@millcreekls.com.

*All employees of MCLS must be fully vaccinated against COVID-19.*

NOTE: This job description is not intended to be all-inclusive. Employee may perform other related duties as negotiated to meet the ongoing needs of the organization.