



Administrative Assistant, Quality Assurance

Job Title: Quality Assurance Administrative Assistant
Schedule: Full-time
Location: Louisville, KY

About Regenerex

Regenerex is a biopharmaceutical company based in Louisville, KY. The mission of Regenerex, LLC is to make the proprietary Facilitating Cell platform technology (FCRx) widely available to treat many disorders with unmet need. The FCRx product eliminates the need for a perfectly matched donor, thereby allowing nearly any candidate for a stem cell transplant to receive the treatment. Hematopoietic stem cell transplantation (HSCT) has been used to successfully treat inherited metabolic enzyme disorders, red blood cell disorders, to induce tolerance to organ transplants and to treat autoimmune disorders such as type 1 diabetes, multiple sclerosis, rheumatoid arthritis and scleroderma.

Regenerex has established a public/private collaboration with the University of Louisville's Institute for Cellular Therapeutics (ICT) to expedite translation of discoveries from bench to bedside. Company and university scientists work together to manufacture the FCRx product and study the mechanism of action of the facilitating cell in this unique translational research environment.

Regenerex requires dedication and a willingness to accept a variety of tasks and responsibilities at all times. Employees must always operate with the highest degree of integrity, be motivated, thoughtful, and dedicated to supporting the long term development of a technology with the potential to improve thousands of lives.

Job Description

The Quality Assurance Administrative Assistant is responsible for Quality Management System (QMS) document control to support the manufacturing program at Regenerex. The Regenerex manufacturing facility is a state-of-the-art, GMP and GTP compliant controlled cleanroom facility designed to enable production of regenerative medicine products.

The Quality Assurance Administrative Assistant will report to the Quality Assurance Manager.

Responsibilities include:

- Quality Management System (QMS) document control including, but not limited to, filing both hard copy and electronic copy records, routing documents for review and approval, posting, copying, and archiving
 - Standard Operating Procedures (SOP) and ancillary documents (e.g., forms, job aids)
 - SOP Table of Contents
 - Nonconformance Report and Planned Deviation forms
 - Corrective Action and Preventive Action forms
 - Change Control forms
 - Validation documents (e.g., plans, protocols, reports)
 - Training forms
 - Document tracking logs and inventories
- Planning for, scheduling, and facilitating meetings using Microsoft Outlook and other scheduling tools as necessary
- Perform additional job related duties as required



Minimum Requirements

- High school diploma required, AS degree preferred
- Two years of related administrative or secretarial work experience
- Proficient in Microsoft applications – Outlook, Word, Excel, PowerPoint
- Excellent grammar required
- Good organization skills required
- Attention to detail necessary
- Ability to work in team and individual environments

Apply: Please submit resume or CV and cover letter to [hiring@regenerex.com](mailto: hiring@regenerex.com)

Regenerex is an equal opportunity employer and prohibits unlawful discrimination.