Quality Assurance Specialist

Job Title: Quality Assurance Specialist
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 partnership 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 Specialist is responsible for assisting in the development and maintenance of Quality Management Systems to support the clinical 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 QA Specialist will be responsible for quality systems including maintenance of document control (scanning and archiving of GMP documentation) and monitoring and maintenance of records (cGMP guidelines, training, pertinent regulations, vendor qualifications, policies and standard operating procedures). The QA Specialist will independently prepare, perform and maintain internal audit/review systems (manufacturing batch records, RedCap database, deviations, quality control analysis and result reports and change controls). This position will require independent authoring of internal regulatory (audit/review) reports for senior leadership review and approval.

Additional duties will include authoring/finalizing protocols provided by third parties, assisting with the development of new labelling systems, and serving as a liaison with laboratory staff. This position requires a high level of autonomy and will be required to search information, independently prepare reports and provide recommendations for the QA unit, interact with a number of outside vendors to obtain regulatory documentation/coordinating the testing of research materials and conducting audits.

The Quality Assurance Specialist will report to the Quality Assurance Manager.
Responsibilities include:

- Maintain Quality Assurance unit document control and records, including:
  - Manufacturing process validations and studies
  - Faculty and staff training records
  - Environmental maintenance and Iso7 GMP facility records
  - Audit and review documentation
  - Vendor qualification documentation, including certification paperwork
  - Policies and Standard Operating Procedures (SOPs)
  - External party training records

- Interact with a number of outside vendors to obtain regulatory documentation and vendor qualification information, coordinate identity testing of research materials, and plan external audits

- Independently prepare, perform and maintain internal audits and reviews requiring a high degree of autonomy; independently author internal regulatory (audit/review) reports for senior leadership review and approval
  - Review Manufacturing batch records for adherence to Good Documentation Practices (GDP) and verification of all calculations for accuracy
  - Independently review deviations and change controls for QA Management review and approval
  - Aid in review of Quality Control analysis and results
  - Monitor / audit web-based clinical trial database (RedCap)

- Prepare Documentation, Protocols and Standard Operating Procedures (SOPs). Research information, independently prepare reports and provide recommendations for the QA unit.
  - Author, revise and track Standard Operating Procedures
  - Assist in authoring and/or finalizing protocols provided by third parties
  - Prepare documentation regarding vendor qualification requirements; independently contact vendors and review vendor qualifications

- Develop regulatory tracking documentation and work with unit senior leadership to ensure timelines achieved

- Act as Quality Assurance liaison with the analytical and manufacturing researchers

- Assist with the development of a new labelling system and issuing labels

- Assist team members with other documentation efforts as necessary

- Perform additional job related duties as required

**Minimum Requirements**

- BS in related field of Science or MS in related field of Science
- 2+ years of experience in a Quality Assurance role; prior experience within a cGTP/cGMP regulated biotech, cell processing (i.e. stem cell or bone marrow processing), tissue bank or pharmaceutical company preferred
- Demonstrated ability to manage and prioritize multiple projects and meet deadlines
- Excellent time management and organizational skills
- Strong written and verbal communication skills

**Additional Qualifications**

- Experience interacting with regulatory bodies a plus
- Understanding of the field of cell therapy processing and cryopreservation preferred
• Exceptional analytical skills and solutions-oriented approach to problem-solving
• Ability to work effectively in a fast-paced, rapidly changing environment
• Demonstrated ability to work independently as well as part of an integrated team
• Good teaching skills and ability to train others preferred
• Flexibility and dedication: Position may require some “off-standard hours” and “on-call” hours to support specific clinical trials, including some nighttime hours to receive product for manufacturing

Apply: Please submit resume or CV and cover letter to hiring@regenerex.com

Regenerex is an equal opportunity employer and prohibits unlawful discrimination.