



Tissue Genesis, LLC is seeking a **Wet Lab Quality Technician** that will become part of a team dedicated to designing, developing, and managing innovative medical devices in the field of regenerative medicine. The Quality Assurance assistant is responsible for implementation and maintenance of the quality system, to include administering documentation and records within an electronic quality management system, performing Quality Control (QC) for product release, and informing the Director of Quality Assurance (DQA) of on-site quality issues. An associate biologist is responsible for carrying out cell culture experiments supporting product release and improvements for TG Medical Products. Associate biologists are responsible for some histological duties relating to adipose tissue, cell cultures, and tissue preparation.

Essential job duties for QA/QC may include:

- Facilitate the maintenance of a quality management system in accordance with 21 CFR Part 820, ISO 13485:2016 and other quality systems as needed
- Administer the eQMS, to include validation and SOP generation
- Assist in quality audits and investigations within defined timelines (CAPA, Complaints, nonconformity reports, etc.)
- Facilitate quality training of TG personnel and contractors
- Assist in assignment and distribution/collection of supplier evaluations and supplier certification management
- Perform on-site recording of QMS data (collect/scan/email/post records)
- Perform QC for product release and distribution activities, including inspection and data analysis
- Assist in onsite office management (receiving mail, recording QMS minutes, setting up team teleconferences)
- Assist with Environmental Compliance to ensure equipment is labeled/maintained per requirements
- Assist with purchasing
- Work collaboratively with the product team and Center management to maintain compliance
- Work with others to ensure timely and appropriate cross-functional alignment for each assigned project

Essential job duties for Associate Biologists may include:

- Coordinate adipose specimen acquisition and lab-related purchasing
- Process adipose specimens and isolate ADSC using cell Isolation systems
- Run assays, assist with preparation of experimental plans, and document and organize data
- Perform cell culturing, including cell banking and functional assays and certain histology and quality assays
- Meet regularly with the respective project team members to assess activities, discuss issues, define expectations, and identify required resources, as well as measure performance and attainment of milestones

## **QUALIFICATIONS & EXPERIENCE:**

### **QUALITY ASSURANCE**

- Minimum of a Bachelor's Degree in Science or Engineering
- Broad understanding of Quality Systems Requirements (QSR), including cGMP (current Good Manufacturing Practices) as outlined by 21 CFR 820 and ISO 13485:2016.
- Experience in a regulated industry preferred (medical device, pharmaceuticals, ISO 17025, etc.)
- In-depth experience working with the principles and techniques of data analysis
- Demonstrates ability to obtain comprehensive understanding of product specifications and functionality
- Strong computer skills, including Microsoft Office Suite (Word, PowerPoint and Excel) and Adobe Acrobat
- Excellent interpersonal skills and problem-solving ability

### **ASSOCIATE BIOLOGIST**

- Bachelor's Degree required (life sciences disciplines strongly preferred)
- Five (5) or more years of relevant experience in biologics/device development/manufacturing