



Tissue Genesis, LLC is seeking a **Medical Device and Inventory Specialist** that will become part of a team dedicated to designing, developing, and managing innovative medical devices in the field of regenerative medicine. The ideal candidate will possess exceptional communication skills, a strong work ethic, a team player mentality and the willingness to learn. The specialist will work with other team members to support current products in the field and ensure that processes are uniform, complete and managed appropriately. The specialist will actively address necessary quality-related service actions produced by the use of TG products in both commercial and research settings, internationally and domestically. The role will be responsible for receiving and shipping components and supplies in an ISO 13485 quality-controlled environment. Additionally, the candidate will lead maintaining physical inventory and records, as well as maintaining the storeroom in a clean, orderly, and ISO auditable condition.

Essential job duties may include:

- Become a technical expert on the current product line
- Write clear, data-driven technical summaries and service reports
- Work collaboratively with QA to maintain compliance
- Apply best practices for maintaining Design History Files (DHF) and Device History Records (DHR) for current products, and periodically update the Device Master File
- Perform investigations and root-cause analyses relating to product non-conformities
- Assist corrective action initiatives (CAPA)
- Work with others to ensure timely and appropriate cross-functional alignment for each assigned project
- Responsible for receiving and shipping of products, components, and supplies in a ISO 13485 quality-controlled environment
- Receive incoming shipments and verify contents against purchase orders and according to acceptance test procedures (ATP). When necessary, administer ATPs to verify goods are acceptable. Issue non-conformity reports if ATPs fail and take ownership to resolve ATP failures.
- Ship outgoing packages according to quality and regulatory procedures
- Maintain storeroom in a clean and orderly, and ISO auditable condition
- Lead in updating inventory records, physical inventory, and interface with accounting regarding inventory
- Track and maintain inventory at multiple external clinical locations in support of company initiatives (e.g. clinical trials, tissue suppliers)
- Excellent team working and people skills
- Be able to travel up to 25% of your time.

QUALIFICATIONS & EXPERIENCE:

- Minimum of a High School Diploma, with a preference for a bachelor's degree in Science or Engineering .
- Previous experience working in a shipping/logistics department strongly desired with experience operating in an ISO environment preferred
- Strong computer skills, including Microsoft Office Suite (Word, PowerPoint and Excel) and Adobe Acrobat
- Strong organization, multi-tasking and problem-solving abilities
- Data entry experience preferred
- Excellent writing & communication skills
- Ability to lift a minimum of 40 lbs.