

Job Title: Quality Incoming Inspector
Department: Quality Department
Reports To: Raw Materials Manager
Date: June 2022
Grade: 7



Job Summary:

Provide customers and TAPEMARK with confidence that incoming materials are controlled and maintained according to specification through sound quality assurance practices.

Duties/Responsibilities:

- Act consistently with Tapemark core values of Excellence, Integrity, and Community to ensure the organization's effectiveness and success.
- Perform raw material receiving in accordance with all internal requirements and external regulations. Perform data entry to receive incoming materials into the inventory database and generate the necessary receiving documents.
- Operates several types of forklifts and material handling equipment to move materials safely into appropriate standard and pushback racking locations.
- Perform inspection and sampling of raw materials including but not limited to various chemicals, controlled substances, API, rolled goods, packaging materials etc. by following proper documentation, safety and handling procedures, TM policies, applicable DEA regulations, cGMP, EU, and FDA guidelines.
- Sample materials utilizing specialized equipment including but not limited to glove boxes, scales, and various sampling tools and utensils.
- Safety procedures will include the use of appropriate Personal Protective Equipment including but not be limited to respirators (half or full face), PAPR hoods (powered air-purifying respirator), SCBA (self-contained breathing apparatus), and chemical protective suits.
- Create and maintain incoming raw material files as needed for materials.
- Generate and process a variety of reports and forms (Initiate NCRs for non-conforming raw materials and finished product, truck bills, COAs, etc.) to assure that Tapemark is following ISO 13485, cGMP, EU, and FDA regulations, Tapemark procedures, and customer requirements.
- Operate a variety of test and measurement equipment required to complete necessary inspections for raw material release.
- Monitor environmental systems assuring compliance to ISO 13485, cGMP, and Tapemark requirements.
- Follows safety policies and procedures to maintain a safe work environment.
- Cooperates with co-workers and managers to develop a team environment where individuals work in an effective and productive manner. Work with Scheduling, Materials, and Project Management to determine material prioritization according to production needs.
- Communicates inspection information to Production and Quality departments on all shifts.

Education and Experience:

- High School diploma, or equivalent
- 2+ years Quality experience preferred.
- 2+ years experience in medical device or pharmaceutical manufacturing environment preferred.
- Must pass appropriate background check to handle, inspect, and sample controlled substances.
- ASQ Quality Improvement Associate or Quality Inspector Certification, preferred.

Preferred Skills/Abilities:

- Knowledge of ISO, cGMP (21CFR 211, 820), and Quality procedures.
- Ability to follow verbal and written instructions.
- Skill and ability to perform work in a thorough and accurate manner.
- Ability to use a wide variety of test and measurement equipment.
- Ability to follow and comply with procedures.
- Ability to develop and produce reports and documentation.
- Ability to make comparisons from visual examples and written instructions to determine product conformance.
- Ability to prioritize and meet deadlines.
- Working knowledge of Microsoft Office programs (Excel, Word, PowerPoint, etc.)
- Skill and ability to communicate effectively at all levels of the organization.
- Ability to read and interpret blueprints and specifications.
- Ability to analyze data and situations and apply appropriate solutions.

Physical Requirements:

<u>Physical Activities</u>	<u>Time</u>
Bending	20%
Kneeling	5%
Lifting (Up to 50 lbs.)	15%
Sitting--Able to move at will	25%
Walking	35%

Employee Signature

Date