

Senior Quality Inspector

POSITION SUMMARY: Coordinate activities in the incoming inspection area and In-process inspection. Inspect parts and subassemblies to ensure compliance with established specifications and inspection instructions. Operate a variety of mechanical, optical, and measurement equipment to determine conformance of components, materials and products to specifications.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Performs visual and mechanical inspections of incoming materials, in-process components/assemblies and final products per applicable engineering and manufacturing documents using tools and equipment such as, but not limited to:
Hand tools (calipers, micrometer, pin gages, etc)
- Smartscope Flash 200
- Stereoscope and metallurgical microscope
- Photographic equipment
- Responsible for ensuring appropriate product segregation and identification is conducted during the incoming inspection and manufacturing process
- Records inspection results in the EtQ system or product traveler. Provide detailed summary report as required.
- Initiates Nonconforming reports for product that does not meet specification requirements. Interface with Engineers to resolve nonconforming material disposition issue and to ensure product quality issues are resolved prior to final product release.
- Write and edit Measure-X inspection programs for SmartScope Flash 200 and troubleshoot programming problems.
- Performs traveler reviews to ensure device compliance to Device master record and Good Documentation Practices (GDP).
- Perform review of engineering documents as requested.
- Perform First Article Inspection on new parts or significant part revisions.
- Assist QE in the investigation of nonconforming material. This may include the investigation of inspection, supplier or manufacturing issues.
- Able to operate helium leak tester and perform hermeticity tests.
- Able to assist inspect electronic assemblies for compliance to IPC standards
- If not certified, can achieve certification

QUALIFICATIONS:

EDUCATION/CERTIFICATION:

- Associate degree in technical field or equivalent
- IPC-610 certification desirable.

EXPERIENCE REQUIRED: Five to seven years with complex mechanical inspection in a medical device/regulated environment with at least two years in programming in computer controlled optical measurement system

REQUIRED KNOWLEDGE:

- Good working knowledge of principles and technique of measurements. Experience in using mechanical inspection instrument and gauges.
- Working knowledge and experience on the use and programming of non-contact multi sensor machine (such as SmartScope)
- Working knowledge and experience on the use of metallurgical microscope for detection of visual defects.

- Good understanding of statistical sampling plans and knowledge of metrology and use of measuring instruments.
- Should have knowledge of spreadsheet, and/or word processing software.
- Demonstrate proficiency in geometric dimensioning & tolerancing (GD&T)
- Solid skills in engineering drawing reading and interpreting (i.e. ASME Y 14.5).

HIGHLY DESIRED KNOWLEDGE:

- Understand regulatory requirements such as FDA QSR, European Active Implantable Medical Device Directive).
- Ability to operate helium leak tester
- Knowledge of printed circuit board assembly to identify visual nonconformities

SKILLS / ABILITIES:

- Excellent people skills, team oriented
- Strong communication and organizational skills
- Knowledge of electronic testing is a plus.
- Inspection involves considerable initiative and ingenuity when only general methods are available.
- Flexibility to adjust to new duties as required.
- Ability to consistently follow and interpret written descriptions of visual acceptance criteria.
- Ability to work with engineers to clarify and improve documented acceptance criteria and acceptance methods