

Job Title: Quality Assurance Engineer

## Job Summary

Design, install and evaluate quality assurance systems and procedures to assure the highest level of product quality for the company; design or specify inspection and testing mechanisms and equipment; analyze production and service standards; recommend revision of specifications when indicated; formulate or help formulate quality assurance policies and procedures and assist in the implementation and adherence to these policies and procedures; provide vendor quality oversight.

# **Duties and responsibilities**

- Conduct or supervise statistical sampling and testing of material processes including metal-forming, punch and die stamping, welding and plastic-injection molding
- Gather and report on inspection data resulting from receiving, in-process, and finished-good inspections
- Gather and report on field failure data of installed products
- Conduct on-site quality system audits of critical suppliers
- Develop test procedures, test criteria, and inspection techniques for supplier components and finished-goods
- Maintain the Safety Data Sheet (SDS) and material certification programs
- Manage the calibration program: ensure that all calibrations are adequate and current, develop internal calibration procedures; arrange for external calibrations when needed
- Conduct training on quality assurance concepts and tools to Manufacturing personnel and others
- Assist in the development of forms and procedures for the quality system

### Qualifications

- Must have a strong knowledge of Quality programs and systems
- Strong project management and reporting skills
- Good understanding of product compliance as required by applicable Regulatory Standards (13485).
- Ability to use measurement tools (calipers, micrometers, various gauging).
- Quality Technician / Engineer Certification from ASQ or equivalent is desired

## **Education and Experience**

 BA/BS Industrial, Mechanical or Quality Engineering or equivalent experience working in a medical product manufacturing environment preferred

#### Desired

- Specific experience in applied design and development of regulated products or Regulatory Affairs field concerning active medical devices
- Experience as a compliance engineer focusing in safety, EMC, Radio, Energy Efficiency, international regulatory certifications or a similar discipline with 3 or more years of high-volume consumer electronics experience
- Experience with ISO and/or FDA compliance issues

#### Skills

- Excellent written and verbal communication skills required to seamlessly work across groups and at all levels
- Working knowledge of Microsoft Office Suite, particularly Excel and Word
- Experience with Epicor a plus
- Good statistical knowledge and application skills

### About this company

Drucker Diagnostics was recently formed by the merger of QBC Diagnostics and The Drucker Company. Our centrifuges accommodate testing needs in medical, research and industrial laboratories. The Horizon line of centrifuges incorporate an exclusive and patented horizontal rotor allowing for quick and easy sample loading with complete horizontal separation. We also provide hematology and parasitology products for a number of diverse markets and applications. The STAR Centrifugal Hematology System is the world's only dry hematology system providing easy and simple operation. The Paralens microscope attachment provides a low cost, portable fluorescence microscopy solution for accurate and sensitive diagnosis.

With a distribution network that operates in over 50 countries, our employees and partners are dedicated and committed to provide innovative solutions for healthier world.

