

## **JOB DESCRIPTION**

**Title:** Quality Engineer  
**Department:** Quality  
**Reports To:** Manager, Quality  
**FLSA:** Exempt  
**Survey Job Code:** 6311 – 6316  
**Survey Job Title:** Quality Engineers

### **Summary:**

Provide support in the development and maintenance of company's quality systems. Support activities related to the production of existing products as well as development and qualification of new products.

### **Essential Duties and Responsibilities**

- Perform nonconformance investigations to determine root cause. Assign and ensure completion of corrective and preventive actions. Complete investigations in a timely manner to ensure customer service levels are maintained.
- Coordinate the reporting and provide trend analysis for nonconformance incidences
- Provide investigation and support for CAPA and Failure Investigation Reports
- Write out of tolerance investigations
- Write FMEAs, review and write protocols and reports for new products
- Perform audits of Production and Receiving Inspection areas
- Support environmental monitoring of cleanroom areas
- Qualify and implement document changes involving product or process changes
- Support Quality Control activities for Receiving Inspection, Production, Finished Goods, and Calibration
- Assist in supervisory activities of Quality Control personnel

### **Education, Training, Skills and Experience Requirements:**

- Minimum 5 years experience in the medical device industry is preferred
- BS in Engineering or related field
- Working knowledge of U.S. and international medical device regulations is desirable
- Working knowledge of EO Sterilization is desirable
- Working knowledge of desktop computer office software and e-mail is required
- Excellent verbal and written communication skills
- Flexibility to handle multiple tasks and meet timelines

### **Physical Demands:**

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. While performing the duties of this job, the employee is regularly required to stand; walk, and sit for extended periods of time.

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Print Name

\_\_\_\_\_  
Employee Signature

\_\_\_\_\_  
Date