

## **Quality Assurance Technician**

Job Location – various locations in US

### **JOB SUMMARY:**

Reporting to the Quality Assurance (QA) Manager, the Quality Assurance Technician is responsible for assisting the Plant QA Manager and Validation Coordinator (if applicable) in ensuring the quality system requirements are met and maintained. This role assists in providing management with information and data on all key aspects of the day-to-day operation, which is used by both plant and corporate management to determine if the quality system is adequate and operating as designed. This information and data is also used to provide guidance for corrective actions and continuous improvement. The QA Technician must effectively interface with Customer Service, Sales, Operations, Engineering and other plant and corporate staff, as well as customers and regulatory personnel.

### **DUTIES AND RESPONSIBILITIES:**

#### Quality, Regulatory & Safety – EO

- Provides information and data reflecting the status of the plant quality system
- Assists with corrective action and process improvement activities and assists in appropriate re-training
- Monitors the quality and integrity of information required for the sterilization process history record (batch record)
- Issues release of processed materials
- Assists in all activities relevant for FDA, customer and regulatory audits
- Assists with the monthly review of Total Quality Management Report
- Assists with audits to ensure FDA/ISO/GMP compliance and to provide basis for continuous improvement
- Assists with Quarterly Environmental monitoring of employees
- Executes equivalency and retrospective re-validation studies/reports
- Assists the Validation Coordinator with validations and calibrations
- Analyzes temperature and humidity probe data
- Other QA/Validation duties as assigned
- Maintains all quality related training programs

#### Quality, Regulatory & Safety – Gamma & e-Beam

- Performs the batch review and approval
- Performs density studies on customer products and complete applicable tote loading diagrams
- Assists the QA Manager in calibration of instruments used in safety and dosimetry systems and performance of quality control procedures

- Assists the QA Manager in scheduled quality audits and “as needed” customer product inspections
- Provides backup support for the QA Manager in a variety of functions
- Reviews and release of production run in MIS system
- Maintains Customer Master Files & Training records
- Conducts Housekeeping audits in accordance with written procedures
- Assists with other tasks assigned by Supervisor

**EDUCATION, EXPERIENCE & SKILL REQUIRED:**

- High School Diploma or a combination of education and experience
- One (1) to 1.5 years of experience working in a sterilization environment preferred
- Must be able to read, write and speak fluent English
- Should be proficient using a computer and be able to analyze data in a database/spreadsheet
- Must be willing to work established shifts
- Must be able to lift a minimum of 50 pounds and perform repetitive bending and lifting motions over a period of time

**SPECIAL REQUIREMENTS:**

- Must be medically approved for respirator use (EO)
- Must be able to tolerate exposure to high temperature and high humidity (120F and 60% RH for 20 minutes) (EO)

**TRAINING REQUIRED:**

Must complete all required training for a “Quality Assurance Technician” outlined in the training manual.