

## Senior Quality Assurance Specialist

Location: US-MD-Gaithersburg

### **Overview:**

The Senior Quality Assurance Specialist is responsible for supporting the development, implementation and administration of the Quality Assurance Program.

### **Responsibilities:**

1. Understand the goals and objectives of the organization; communicates, develops, motivates, and assists with staff training, as necessary, to help achieve the company's Quality goals.
2. Assists with development of standard operating procedures applicable to Quality System Regulations.
3. Performs evaluation of approved production processes, identifies gaps in processes or documentation, validation documentation and other supporting components that may be required in support of production to support the expansion of ISO 13485:2003 product lines.
4. Assists with the administration of corrective and preventive action in accordance with standard operating procedures.
5. Advises internal customers to ensure ISO compliance with product development goals according to company SOPs.
6. Functions as a lead auditor in assisting with both internal audits and vendor audits to ensure compliance to documented procedures. Supports the department with resolution and monitoring of any identified action items.
7. Travel will be required.
8. Assists with the preparation and analysis of data for management reviews and monthly metrics. Assists with the implementation of any resultant action items.
9. Assists with training staff in accordance with quality-related policies and procedures as requested.
10. Performs other ancillary duties as assigned.

### **Qualifications:**

#### **Education and Experience:**

- A Bachelor's Degree in appropriate technical discipline, including biological, chemical sciences or similar disciplines is required.
- 5 to 8 years' experience in field of quality assurance with ISO 13485 and GXP is required.
- Experience with CE Marking preferred.
- Good computer skills are required.

#### **Knowledge, Skills and Abilities:**

- Excellent interpersonal and communications skills.
- Excellent organization and analytical skills.
- Ability to work alone or within a cross-functional team environment.