**Job Posting**

Quality Assurance & Documentation Specialist

**Department**: Quality Assurance

**Function**: Responsible for QMS and ISO system development, implementation and compliance. Responsible for registration of the products, the factory and the quality system with the appropriate government authorities, registration agencies and notified bodies.

**SUCCESS FACTORS**

**Key Performance measure:** The cycle time to correct identified shortcomings in our products and processes.

**Education requirements**: A ssociates degree in a technical or life science field is preferred.

**Experience**: At least 2 years relevant experience.

**Abilities**: Must have a working knowledge of quality systems and quality systems audits.

**Other Attributes**: The Quality Assurance & Documentation Specialist must lead the effort to continuously improve quality system.

**JOB ELEMENTS**

1) Certify that every production lot is manufactured according to its device master record. Review the DHR and Release for Distribution forms at our primary sub-contractors to verify that the records are complete and consistent with the DMR.

2) Review and approve key events and processes; product development, manufacturing, distribution, market release, marketing literature and clinical trials.

3) Oversee the switch to a new ISO notified body

4) Write and review procedures for quality assurance and other functional elements of the quality system.

5) Own the Documentation process to create and control Device Master Record, Design History File, Company Procedures records and standards.

6) Manage the Documentation File system. Ensure that the file system integrity is maintained whether on paper or computer.

7) Perform internal audits. Recommend corrective action to findings. Follow up on previously identified non-conformances or program deficiencies for the purpose of verifying successful completion of action and for closing previous audits.

8) Perform supplier audits: Recommend corrective action to findings. Follow up on previously identified non-conformances or program deficiencies for the purpose of verifying successful completion of action and for closing previous audits.

9) Monitor the effectiveness of the quality system performance through the Complaint System, CAPA System, internal audits and Management Review System.

10) Act as the management rep.

11) Maintain Establishment Registration for Circadiance.

12) Apply for and obtain the suitable certifications and registrations for all appropriate products. Determine the regulatory approval strategy for Circadiance products (FDA, CE, etc.) and manage the approval and device list process. Interface with hardware engineering for all safety registrations and certifications.

13) Develop and maintain the regulatory files for the company. Keep regulatory registrations up to date. Communicate with customers, distributors and field sales people the regulatory status of the company and its products.

14) Escort regulatory and certification agency representative if they come to our site.

15) Participate in QMS/ISO training to ensure that all personnel understand the management commitment to QMS compliance.

16) Establish metrics for Quality Assurance and Regulatory and report on those metrics.