



Quality Systems Coordinator

The Quality Systems Coordinator is responsible for the maintenance of, and improvements to, Simbex' ISO13485 compliant Quality Management System (QMS). This position ensures that the QMS is being implemented according to established standard operating procedures and works with the product development teams to ensure products are being developed and manufactured under appropriate controls.

ESSENTIAL FUNCTIONS

- Partner with the project managers to ensure product development adheres to established and documented best practices and standard operating procedures.
- Oversee the development and maintenance of procedures and policies required for the QMS.
- Provide introductory and ongoing training to all employees on the QMS.
- Plan and execute internal quality audits of Simbex processes and procedures.
- Plan and oversee external quality audits of vendors/suppliers if necessary.
- Oversee customer and agency audits. Ensure that appropriate documentation is established throughout the product development lifecycle.
- Lead the quarterly QMS review meeting and ensure quality objectives are established and met.
- Ensures that all quality documentation meet appropriate documentation standards and follows good documentation practices.
- Ensure that staff are appropriately qualified to perform special processes.
- Ensure record retention and maintenance of all quality system documentation, including change orders, work orders, deviation requests, etc.
- Implements and maintains the project quality plan on assigned projects, and ensures that customers execute documents as defined in the project specific quality plans.
- Oversees the corrective action process and ensures that non-conformities are appropriately documented and follow-up activities are executed.
- Assume lead role in assuring compliance to local/federal regulations are being followed.
- Oversee equipment Calibration system and coordination of services with external vendor.

EDUCATION AND EXPERIENCE

- Bachelor's degree with a minimum of 2 years quality related experience or Associates degree with 4 years of quality related experience, or a minimum of 5 years quality related experience.
- Good organizational skills and strong attention to detail. Familiarity with product development lifecycle activities including requirements management, risk assessment, validation and verification and manufacturing.
- Experience managing design history files and device master records.
- Excellent communication skills, including experience developing and delivering training programs.
- Lean/Six Sigma certification/training a plus.
- Experience with product risk assessment methodologies is required.
- Experience in Software Quality Assurance practices a plus.
- Strong Microsoft Word, Excel and Powerpoint is required.
- Experience with Microsoft SharePoint is a plus.

- Familiarity with product design and development
- Familiarity with Good Manufacturing Practices
- ISO13485 experience is highly desirable