Quality Assurance Manager at CTL Amedica

CTL Amedica is an ISO 13485 certified and FDA registered Medical Device Company with offices in Addison, Texas. CTL designs, manufactures, and distributes medical device products and systems for spinal surgeons; specifically implants and devices.

Job Description:

This position is responsible for providing leadership to the Quality staff and for supporting Quality System activities throughout the organization. Responsible for reviewing and interpreting Quality Control & Assurance requirements based on regulations and standards and providing compliance direction to the organization. The Quality Assurance Manager will be the authorized management representative for the organization and will be the primary interface with external regulatory agencies.

Duties and Responsibilities:

- Develop Quality System department goals and objectives with associated operating budget to support department activities and corporate initiatives.
- Build a strong Quality Control & Assurance team by hiring qualified candidates, establishing, and actively managing performance expectations.
- Prepare and deliver training and orientations on global quality system requirements and company processes to employees.
- Interface with FDA, EU notified bodies, Authorized Representatives, and government agencies as necessary to ensure currency of applicable standards. Coordinate external audits from FDA, EU and other government agencies as required. Assist with registration activities and formulate/communicate responses to audit findings.
- Lead, plan, coordinate, and conduct internal and supplier audits.
- Perform all formal responsibilities of a Lead Auditor including completing an audit report and issuing formal corrective actions.
- Performs audits to 21CFR820, ISO13485:2016, and ISO14971 standards and regulations at the supplier's site or remotely as required by CTL Amedica Procedures.
- Reviews supplier audit corrective action plans for acceptance and works with suppliers to have acceptable corrective action plans.
- Oversees Non-Conforming Material/MRB processes to appropriately disposition non-conforming product and drive corrective actions.
- Establishes/maintains compliant product labeling process.
- Oversees product release activities.
- Review drawing/document changes and DHF's for compliance with applicable regulations and standards.
- Maintains a safe and professional work environment.
- Other duties as assigned.

Qualifications/Skills

- Bachelor's degree in Engineering or related field
- 5 years of relevant experience in the medical device industry (preferred)

- Able to be certified as a certified quality auditor within one year of employment
- 5+ years of proven leadership skills, including experience setting goals, providing positive and constructive feedback, and improving business results
- Strong knowledge, understanding and experience implementing 21CFR820, ISO13485:2016, and ISO14971. Must be able to interpret device law into workable, efficient, and effective practices and procedures.
- Experience with reporting and data analytics
- Experience serving as Quality Management Representative.
- Experience implementing Unique Device Identifier requirements for medical devices.
- Expertise with process/software validation, Gage R&R, and process capability.
- Effective technical/leadership skills; decisive, strategic, and able to lead, motivate and inspire others.
- Exceptional computer skills including operation of Microsoft Office applications.
- Manages up to 10 direct reports.

Travel Requirements: Up to 15%

This is a full-time hourly position. Benefits include 401K with employer match, great health plan, dental and vision, paid sick days, holidays, and vacation.

If you would like to apply or have further questions, please email SSuh@CTLAmedica.com