QUALITY SYSTEMS MANAGER

POSITION SUMMARY:

The Quality Systems Manager is responsible for providing leadership to the Quality Systems staff and for supporting Quality System activities throughout the organization. This position is responsible for reviewing and interpreting Quality System requirements based on regulations and standards and providing compliance direction to the organization. The Quality System 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 Systems 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 Representative 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.
- Plan, coordinate, and execute quality system internal audits and supplier assessment/audit activities.
- Manage Non-Conforming Material/MRB processes to appropriately disposition non-conforming product, and drive corrective actions.
- Establishes/maintains compliant product labeling process.
- Manages product release activities.
- Review drawing/document changes for compliance with applicable regulations and standards.

ESSENTIAL SKILLS, EXPERIENCE AND QUALIFICATIONS:

- Bachelor's degree in Engineering
- 5 years of relevant experience in the medical device industry and staff management.
- 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 serving as Quality System 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.
- Previous experience in the spine orthopedics industry preferred
- Manages up to 10 direct reports.

****To apply for this opportunity, please send a resume and cover letter to careers@ctlmed.com, referencing the Quality Systems Manager position.**