Quality Engineer

Position Summary:
Quality Engineering support for product development, manufacturing operations, quality systems, and supplier management activities. This position is expected to take a hands-on approach on all aspects of quality engineering and quality systems.

Educational – Experience Requirements:
Bachelor's degree in Engineering, Science or similar field.

Minimum Experience:

- 2+ years related experience in the medical device industry required.
- Results driven, collaborative team player capable of working well with others, as well as autonomously with little direction.
- Ability to adapt to dynamic situations and adjust as we grow.
- Basic understanding of the medical device industry including 21 CFR Part 820 and ISO 13485.
- Basic understanding of mechanical, electrical, and/or software engineering.

Essential Duties and Responsibilities
The essential functions include, but are not limited to the following:

- Provide all around Quality Engineering support to Project Teams/Manufacturing.
- Provide daily quality support to incoming inspection and manufacturing activities.
- Independently provide knowledge of Evident Vascular Quality Management System as it pertains manufacturing operations as well as dealing with supplier quality.
- Support Quality review and approval of technical documentation for design and development, manufacturing, and risk management through applying applicable company procedures and regulatory requirements.
- Assists in the maintenance of the Quality Management System (QMS) and all associated documents.
    - Document Control: Support processing of changes and maintenance of document control systems and procedures. Resolve technical issues in a timely manner.
    - Training: Administer and manage quality system training for all employees.
- Ensure that document release packages are accurate, complete, and current and that all documents are maintained and controlled.
- Maintain quality system and participate in internal/external audits to ensure compliance with FDA regulations and ISO 13485.
- Initiate changes to improve quality systems and processes.
- Support the supplier assessment/qualification and maintenance activities.
- Evaluate quality performance data and present results to the management team.

Pay range in California, United States
Exact compensation may vary based on skills, experience, and location. Base salary: $120,000 - $180,000

Note:
This job description in no way states or implies that these are the only duties to be performed by the employee(s) incumbent in this position. Employees will be required to follow any other job-related instructions and to perform any other job-related duties requested by any person authorized to give instructions or assignments. All duties and responsibilities are essential functions and requirements and are subject to possible modification to reasonably accommodate individuals with disabilities. To perform this job successfully, the incumbents will possess the skills, aptitudes, and abilities to perform each duty proficiently. Some requirements may exclude individuals who pose a direct threat or significant risk to the health or safety of themselves or others. The requirements listed in this document are the minimum levels of knowledge, skills, or abilities.

Please reach out to info@evidentvascular.com if you're interested in learning more about this position.