

Senior Quality Engineer

Why RevMedica:

RevMedica is an early stage, pre-revenue surgical device startup. You will be the second full time employee, reporting directly to the CEO and CTO. In this role, you will have a chance to rapidly grow as the company grows. An ideal candidate will ultimately manage our quality management system and ensure robust compliance throughout the product development process.

Responsibilities Include:

- Supports and maintains the quality system and is able to make quality system recommendations and follow through to implementation to address issues found.
- Work with other departments to resolve issues related to material and process quality, including FMEA, DOE.
- Suggests recommendations on quality concerns, trends and costs.
- Perform Validations (IQ, OQ, PQ, MSA, CQ) in accordance with company SOP's.
- Ability to manage the customer complaint system. Performs analysis of customer complaints. Initiate corrective action requests on discrepant product/processes and verify adequacy and accuracy of corrective action taken internally and/or externally.
- Follow up on CAR effectiveness.
- Schedules and conducts and/or coordinates internal and external audits; prepares and issues summarized reports; maintains quality surveillance of suppliers. Interface with supplier quality representatives concerning problems with quality and assure that effective corrective action is implemented.
- Participates in New Product Development to assure quality considerations are adequately covered in the design, testing, and release of materials, components, and products.
- Analyzes causes of defects and corrective actions.
- May supervise and schedule work of Quality personnel and/or other subordinates as assigned.
- Design methods for evaluating product quality; establishes test programs to evaluate materials, processes and products. Collect, analyze and interpret statistical data.
- Develop Control Plans, Inspection Instructions and other documents as needed to effectively manage product/process quality.
- Develop and review documented operating procedures associated with material inspection or processes.
- Review and Approve Engineering Change Orders.

Nice to Have

- Experience in polymer material selection
- Ability to manage multiple tasks and projects
- Medical device or healthcare industry experience
- Experience creating technical, written content
- Demonstrated data analysis skills
- Ability to interpret technical drawings
- Demonstrated written and verbal communication skills
- Strong interpersonal skills
- Strong understanding of mechanical engineering principles and methodologies
- Effective problem-solving skills
- High degree of initiative and self-motivation
- Experience solving ambiguous problems
- Experience with the design and manufacture of medical devices
- Experience in product design and development in an R&D environment

Must Have: Minimum Requirements

- Bachelor's Degree in Engineering, Science or technical field with 4+ years of work experience in Engineering and/or Quality OR Master's Degree Engineering, Science or technical field with 2+ years of work experience in Engineering and/or Quality.
- Process Validation and Root Cause Analysis (CAPA/NCR) experience a must.
- Experience working within a GMP environment a must.