



<https://www.biolink360.com/job/qms-quality-manager/>

## Quality Assurance Manager- Med Device

### Description

Position title: Quality/QMS Manager- Southern CT  
Reports to: Director of Operations  
Position type: Hybrid  
Salary: 120-170K

We are seeking a dynamic Quality leader with life science background. This is a long standing company, privately held medical device company that is a leader in their space. We are looking for a Quality Manager who will have responsibility over all things Quality, and work closely with the Senior Leadership team as an in house subject matter expert.

### Responsibilities

- Develops and implements quality systems and practices to assure compliance with FDA, ISO and other required regulatory bodies, serving as the company Quality Management Representative.
- Manages the development and implementation of goals, objectives, policies, procedures, and systems. Communicates quality goals, metrics, and standards to the organization
- Identify quality related organization wide training needs and develop programs. Assist in delivering training.
- Develops customer and internal inspection-based metrics. Identifies trends and develops action plans.
- Monitors supplier quality performance and initiates programs to ensure suppliers meet organization and customer expectations.
- Assists in program launch, process qualification and equipment validation.

### Qualifications

- Bachelor's degree (B. S.) in Mechanical Engineering or related technical field or equivalent related experience.
- Minimum of 8 years experience in quality engineering in the medical device, dentistry, veterinary medicine or similar industry.
- Statistical problem solving, statistical sampling technique, SQC, SPC and higher-level statistical problem solving (DOE, t Test, f Test, etc.).
- Experience in materials science, material specification and tolerancing and raw material processing technique.
- Experience with manufacturing processes in a high-volume, tight tolerance precision manufacturing environment.
- Management and supervisory experience required.
- ISO 13485 quality system or equivalent experience.

### Hiring organization

BioLink 360

### Employment Type

Full-time

### Industry

Healthcare/Medical Products

### Job Location

Milford, CT

### Base Salary

\$ 120,000 - \$ 180,000

### Date posted

January 5, 2024