



The Röchling Group has been shaping industry. Worldwide. For more than 200 years. We transform the lives of people every day with our customized plastics: they reduce the weight of cars, make medication packaging more secure and improve industrial applications. Our workforce of 11,737 people is located in the places where our customers are – in 92 locations in 25 countries.

Röchling Medical is a preferred supplier and development partner to leading pharmaceutical, biotech and medical technology companies worldwide. At six locations in Germany, USA and China, we develop and manufacture tailor-made pharmaceutical packaging and administration solutions, consumables for medical diagnostics as well as sophisticated components and assemblies for medical devices under clean room conditions.

The Rochester location is Röchling Medical's center of excellence for the production of surgical forceps for minimally invasive electrosurgical devices and also offers a broad portfolio of plastic injection molded parts and value-added assembly work for the medical industry. With its technical expertise, the team in Rochester is able to support customers as a contract manufacturer for the entire product lifecycle from concept to complete approved medical device.

The Quality Engineer/Supplier QE is responsible for ensuring that products and processes meet established quality standards by identifying shortfalls, developing corrective measures, and implementing quality control systems, acceptance sampling, validations of injection molded, medical device and purchased components used in validated processes.

Quality Engineer

Where we need you

Essential Duties/Responsibilities:

- Support Engineering Development and Validation activities.
- o IQ, OQ, PQ Submissions
- Document IQ, OQ, PQ Protocols
- Document IQ, OQ, PQ Submissions
- Develop PPAP Qualification Documentation per customer PPAP Requirements.
- o Develop Control Plans
- o Develop PFMEA
- o Develop Process Flow

- o Perform Data Analysis using Minitab
- o Capability Analysis
- o ANOVA Studies
- o Measurement System Analysis (MSA)
- Using Problem Solving & Root-cause Analysis Tools:
 - o 5-why Analysis
 - o Fishbone Analysis
 - o Scheduling Brainstorm sessions
 - o Documenting Continuous Improvement Activities
- Internal Auditor
- Monitoring and analyzing quality performance

How to convince us

Required Skills/Abilities: · Excellent verbal and written communication skills. · Excellent interpersonal and customer service skills. · Excellent organizational skills and attention to detail. · Strong analytical and problem-solving skills. · Strong leadership skills. · Ability to prioritize tasks and to delegate them when appropriate. · Ability to function well in a high-paced and at times stressful environment. · Proficient with Microsoft Office Suite and Minitab software. · Proficient print reading skills

Education and Experience: BS degree preferred. At least 5 years' related experience required.

Physical Requirements: Prolonged periods of sitting at a desk and working on a computer. Must be able to lift up to 15 pounds at times. Visual acuity for inspections, color differentiation, reading electronic documentation.

Work Environment: Manufacturing environment requiring appropriate eye protection. Exposure to high noise level in the work environment requiring hearing protection. Gowning and sanitation for manufacturing in a clean room, as applicable.

What we offer

Benefits: 401(k) 401(k) matching Dental insurance Employee assistance program Flexible schedule Health insurance Health savings account Life insurance Paid time off Professional development assistance Tuition reimbursement Vision insurance

Röchling Medical Rochester (RMR) is an Equal Opportunity Employer. RMR does not discriminate on the basis of race, religion, color, sex, gender identity, sexual orientation, age, non-disqualifying physical or mental disability, national origin, veteran status or any other basis covered by appropriate law. All employment is decided on the basis of qualifications, merit, and business need.