Röchling

Medical

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.

Since its founding in 1997, Röchling Medical Lancaster has focused on establishing itself as a vertically integrated contract manufacturer for the medical device industry. By integrating metal and plastic processing technologies in a state-of-the-art production environment, Röchling Medical Lancaster is able to make its customers' supply chains more efficient and produce medical devices in a cost-optimized manner.

In the Medical division, you will work with our customers to make pioneering contributions to disease prevention and health restoration worldwide. We offer a wide selection of custom-tailored components through to complete systems. Here we take the product to manufacturing. Check out a quick video of our facility and some of the work done here. Copy and Paste into browser: https://youtu.be/seRnkLPeYLo

Quality Assurance Engineer II

Where we need you

SUMMARY Provides support for and leadership of critical quality assurance activities that are a part of new business quality planning, ongoing manufacturing and quality system support, change activities, supplier management, and process improvements in a regulated medical device manufacturing environment.

ESSENTIAL DUTIES AND RESPONSIBILITIES

As part of a project team bringing new products into the QMS, acts as the quality assurance representative assuring the planning and completion of quality system required activities. These products may be finished devices or more complex device components that cross multiple manufacturing technologies. Acts as the primary liaison with QA peers at client organizations in the day-to-day maintenance of the business. Work with Engineering and Engineering Project Management during change activities, utilizing appropriate quality tools to ensure changes are thoroughly evaluated for elements of risk, validation status, and effects on customer requirements. Ensures that changes are controlled and include a clear implementation plan. Prepares, executes, and documents various quality related studies and exercises such as FMEAs, MSAs, Validation Plans, Capability Studies. Leads cross functional teams in the completion of these activities. Owns Corrective and Preventive Actions or Complaints and completes investigations, documents corrective action plans, and monitors progress toward closure within timeframes set forth in documented procedures. Manages the qualification of critical vendors including the planning, execution, and documentation of testing activities to assure that provided products or services will meet documented requirements. May serve in any several roles during regulatory and internal audits including scribe, back room, and auditee roles as required. Summarizes, graphs and reports quality system data to prepare presentation materials for Management Review meetings. Leads or participates in supplier audits. Performs training in or acts as a resource or internal consultant on Quality System procedures and processes,

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quality analysis techniques, or statistical methods. Creates or revises quality system SOPs as assigned. Other duties may be assigned.

How to convince us

Bachelor's degree (BS) from four-year college or university; plus a minimum of five (5) years relevant experience, preferably in medical device or pharmaceutical manufacturing. An equivalent combination of the above education and/or experience.

Additionally 5+ years hands on experience in a GMP environment; Valid drivers license; ASQ Quality Manager, Quality Engineer or Auditor Certifications a plus; Six Sigma Green or Black Belt Training a plus; Ability to occasionally travel to visit customers and/or suppliers

What we offer

401(k) plus matching; Dental insurance; an Employee assistance program; Health insurance; Health savings account; Life insurance; Paid time off; Professional development assistance; Referral program; Tuition reimbursement; and Vision insurance

Do you want to join our team? Please send your resume for consideration.

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