https://appleassoc.com/job/quality-engineer-medical-device-industry-new-hampshire-2/

Supplier Quality Engineer – Medical Device Industry – New Hampshire

Hiring organization
Apple & Associates

Employment Type
Full-time

Industry
Medical Device

Job Location
Laconia, NH

Base Salary
$ 70000 - $ 85000

Education

- Bachelor's degree in Engineering.
- 3 – 5 years of experience in Quality, Supplier Quality, Supply Chain or related process driven field.

Date posted
June 22, 2021

Valid through
31.07.2021

Description

A Leading medical device contract manufacturer with 20 sites globally, a majority located in the USA, is seeking a Supplier Quality Engineer for this NH Site.

The Supplier Quality Engineer will support this plant with about 100 FTEs over 3 shifts, serving as the sole supplier quality engineer who will be the sole SQE onsite, dealing with 300 suppliers (10 critical suppliers) traveling to 1 supplier audit per month. Most suppliers are in New England but some are sprinkled throughout the U.S. The main medical device products produced in this facility are surgical orthoscopic and endoscopic instruments with significant metal machining processes.

The primary purpose of this position is to facilitate the risk-based supplier management process for the site, lead the critical supplier-related projects, and support supplier non-conformances and requests for change. This position will also be responsible for performing GMP/ISO audits on suppliers, proposing improvements to their quality system and tracking the closure of any audit related non-conformance.

This Material involved with a diverse and exciting range of Supplier Types (Service and Material).

Responsibilities

Supplier Quality Engineer Duties:

Leadership

- Develops, maintains and improves the supplier management program while assuring alignment and supporting Supply Chain Organization initiatives and policies
- Manage and Suggest Continuous Improvement project/strategies (Based on Supplier OTD and Supplier Quality Metrics) and report plans/updates during SQM and Management Reviews

Core Competencies/Skills Required:

- BS degree in engineering, a technical or scientific discipline; or with exception, CQE certifications / 6 plus years' experience

- Quality Engineering certification (CQE) preferred or equivalent body of knowledge in areas which include, but are not limited to Statistics, SPC, Geometric Dimensioning/Tolerancing; Sampling, Design of Experiments, etc. Ability to analyze, understand and effectively communicate this technical material. Experience with Lean Manufacturing and Six Sigma is a plus
- 3-8 years experience in the Medical Device or other regulated industry, such as QSR and ISO 13485, with increasing responsibility
- Experience with FDA and ISO 13485 Certification inspections is a plus
- Strong written and verbal communication skills
- Ability to work well independently and with fellow team members
- Attention to detail and organization skills
- Computer skills with proficiency in Microsoft Outlook and Microsoft Office, Minitab preferred

Supplier Quality Functional Execution

- Acts as a quality representative for Supplier Quality activities, both troubleshooting Supplier-CAPA and continuous improvement initiatives (inclusive of Inspection and sampling reduction projects).
- Manages supplier corrective action system (investigation, documentation and implementation of corrective action and the verification of their effectiveness)
- Design and/or specify inspection methods, tools and test equipment to ensure product quality and design integrity are appropriately maintained. Also, implements appropriate inspection sampling plans using statistical methods.
- Reviews and approves changes to supplier related documents (procedures, drawings, etc.) with support from the Technical Groups
- Perform component qualifications, risk assessments and first article inspections (as required) prior to the supplier implementing and /or performing the change.
- Participate in suppliers design review, product validation design verification, Risk Management plans/reports (dFMEA, pFMEA)
- Perform risk analysis for existing and new raw materials/components
- Develop and conduct statistically designed experiments to determine sources of materials/ component variability so the product quality is maintained or improved with support from VS Technical Groups
- Assist with Supplier Transfer projects from planning stage through qualification.
- Manages the supplier requests for product and process changes

Supplier Quality Compliance

- Adheres to company Values and suitably represents the company’s best interests during Supplier engagements and Audits.
- Complies with all safety and quality requirements.

- Supports supply chain activities and assist with ensuring procedures are compliant to applicable sections of FDA quality system regulation and ISO 13485 regulation.
- Performs other functions as required.

Qualifications

Supplier Quality Core Competencies/Skills Required:

- Bachelor's degree in Engineering.
- 3 – 5 years of experience in Quality, Supplier Quality, Supply Chain or related process driven field.
- Must have experience in a regulated environment, medical device is a plus
- Six Sigma Black Belt Certified, Certified Quality Engineer or Auditor preferred
- Negotiating, influence and leadership abilities.
- Computer knowledge: MS Excel, MS Word, MS Power Point, Minitab.
- Knowledge of ISO 13485 and FDA QSR
- Quality System Audits knowledge.
- Good manufacturing and documentation practices.
- Drawings and blueprints knowledge.
- Measurement and test equipment knowledge.
- Excellent communication (written and verbal) skills with internal and external customers.
- Presentation skills.
- Ability to work in a matrix organization, strong analytical skills.
- Problem solving and skills.
- Proven leadership, communication, and project management.

Contacts

Kristen Grant – kgrant@appleassoc.com