



Job Title: Quality Engineer
Department: Quality
Reports To: Quality Engineering Manager
Direct Reports: No
FLSA Status: Exempt

Job Summary

Reporting to the Quality Engineering Manager, this person will provide ongoing support to the manufacturing team in an effort to maximise production quality performance, including identifying root cause, implementing corrective/preventive action on all quality issues in production. Scope of role will also include addressing any customer related issues identified in the manufacturing process and validation of new processes/products

Job Duties

- Review, update and maintain existing quality management processes and procedures.
- Maintain detailed and accurate quality records, data analysis and documentation.
- Ensure quality inspection instruments are accurate and regularly calibrated, tested and audited.
- Ensure new product introductions and change controls are effectively managed in accordance with the ISO requirements when appropriate.
- Other duties as assigned.

Impact

- Ensure that the Company retains ISO accreditation.
- Ensure quality standards are adhered to, and all production processes are carried out according to procedures.
- Raise quality profile and operating standards within the business.
- Initiate and drive continuous improvement programs.

Independent Judgment

- Prepare and execute process / product validations.
- Support the introduction of new product lines through development of product inspection plans, process FMEAs and risk management plans.
- Conduct internal audits.

Analysis/Problem Solving

- Non-conforming material, customer complaints, CAPA investigation, analysis and improvement.
- Data analysis and trending, statistical process control, root cause analysis and the implementation of corrective actions.
- Ability to interpret a variety of instructions furnished in written, diagram, or schedule form.

Communication

- Host audits of the Company's operations by external bodies (e.g. audits from customers, audits relating to certification to official standard e.g. ISO 9001, ISO 13458)
- Ability to respond to common inquiries or complaints from external customers, internal customers and management.
- Ability to effectively present information as required.
- Capable of coaching and mentoring others.
- Excellent written and verbal communication skills as well as the ability to accurately document work performed.

Skills/Technical Skills

- Have good data analysis capabilities and be familiar with statistical software (ideally Minitab).

- Demonstrate knowledge of 6 sigma methodology and structured systematic route cause problem solving.
- Knowledge of computer systems; integrated manufacturing systems; word processing and spread sheets.

Knowledge

- Understands regulated type industries.
- Knowledge of medical device manufacturer and supplies knowledge.
- World-class manufacturing knowledge.

Physical Requirements

- While performing the duties of this job, the employee is occasionally required to stand; walk; sit; use hands to finger, handle, or feel; reach with hands and arms; and talk or hear. Specific vision abilities required by this job include close vision, distance vision, color vision, peripheral vision, depth perception, and ability to adjust focus.

Education

- Bachelor's Degree (level 8) in Quality Assurance or a related discipline

Experience

- Minimum 3 - 4 years prior experience in a similar role in a regulated environment, preferably in either the Medical, Packaging or Technological industries.