



SUPERMAX
Healthcare Limited

Job Title:

Group QA, RA & Technical Executive

Reporting to:

Group QA, RA & Technical Manager

Place of Work:

Supermax Healthcare Limited Head Office, Titan Drive, Fengate, Peterborough, PE1 5XN

Level of responsibility:

Group QA, RA & Technical Executive Supports the QA, RA & Technical Manager.

Purpose of Job:

The purpose is to take a lead role in the Quality, Health & Safety, Technical and Regulatory Compliance functions for the company. The general purpose is to support the QA, RA & Technical Manager by driving resolution of Quality, Health & Safety and Regulatory issues.

Key Roles & Responsibilities:

- To maintain and continuously improve the company's Quality Management System, QMS, with the target of maintaining accreditations to standards, including LSAS, ISO 9001, and ISO 13485.
- To maintain close working relationships with operations and the wider business to enable effective, timely resolutions of quality issues and promote continual improvements.
- To maintain customer complaints, CAPA and non-conformance systems, looking for root cause and driving remedial action.
- To assist in the development of the business H&S Management System, with the target of ensuring that the site is meeting all requirements of the Health & Safety at Work Act 1974. To deal with any H&S issues that arise in conjunction with the Management team.
- To ensure that the business is compliant with all regulations with regard to product markets that the business actively supports, acting on Non-Conformance in a timely manner.
- Ensure all technical information and files are up-to-date and in line with all new and existing legislation requirements.
- Support in the delivery of our audit processes and providing proof documentation to 3rd party auditors.
- Manage and control all product inspection activity both pre- and post-shipment.
- Responsible for the completion of all relevant customer questionnaires.
- Maintenance of the business in-house test area.
- Providing the relevant support to the Sales & Customer Services teams as well as our customer base.
- Work with Purchasing to ensure all products have the necessary technical and test data for sign-off.
- To provide QA cover in the absence of the line Manager.

Areas of Responsibility:

Quality:

- Maintenance & review of Quality Management Systems (QMS) including Policies, Procedures and processes.
- Conduct Internal Quality Audits, promoting resolution of issues.
- Assist with Quality audits from Standard Accreditation Organisations and Notified Bodies. Conduct External Audits of our suppliers.
- Resolution of complaints via an effective CAPA system and reporting on its efficacy, including introducing processes to ensure improvement and reduction in complaint levels (Route Cause Analysis).
- Management of the Corrective & Preventative Action (CAPA) System, concession system and the change control system.
- Maintenance of the Risk Management processes, including HACCP, Hazard Analysis and Critical Control Points.
To maintain a Goods In and Goods Out system, with a right first time approach.
- To assist operations in adhering to GMP that conforms to accredited standards, and to audit compliance.
- To assist purchasing in ensuring that suppliers provide products and components that meet the required standards.
- To support Sales in providing appropriate quality information, managing customer audits and assisting with other customer visits.
- To monitor and report KPI performance.
- To assist business Continuous Improvement strategies.
- Conduct training of Quality Systems as required. Ensure that training plans are in place and monitored. Identify areas for improvement.

Regulatory Affairs / Compliance

- To maintain product technical files including set-up of new products and changes to changes to existing products and maintenance of records.
- Monitor the legislative developments for regulations affecting key internal and external stakeholders and report in a timely manner.
- Effectively communicate to the business legislation impacting across all regulated product categories and classifications.
- Review new products and product changes as part of the business systems.
- Provide technical and regulatory expertise to sales teams so that all products are compliant.
- Conduct any training of regulatory affairs as appropriate.

Health & Safety

- Assist the management of business H&S, ensuring processes are place, reviewed and standards are being met.
- To work with teams to identify potential hazards across the site and develop strategies to minimise these.
- To promote strong health and safety culture across the business.
- Carry out internal H&S audits.
- To assist the creation, maintenance and review of policies and procedures, including Company Health & Safety Policy.
- Production of suitable & sufficient safe systems of work for all activities.
- Involvement with industry safety programs / initiatives.
- Investigation and report near misses, accidents & incidents to allow lessons to be learned. Keep up to date records of all reportable accidents and incidents.
- Training including H&S inductions and briefings.

Other Duties:

- Provide support for the QA, RA & Technical Manager as required. Conduct any other business related activities as required and directed by management.

Essential requirements:

- Can-do attitude, determination to succeed.
- Experience of working within a QA, QC or similar role.
- Experience with working with ISO 9001 (and ideally ISO 13485).
- Experience of Internal Auditing.
- HACCP experience would be valuable.
- Computer literacy – Microsoft Excel, word and power-point.
- Good level of oral and written communication skills.

Normal hours of work:

Normal hours of work are 8:45 to 17:15 per day, Monday to Friday with 45 minutes for lunch each day. There may be a requirement to work outside of these hours as the business requirements dictate.

Pay:

Attractive Salary plus annual bonus scheme

Holiday Entitlement:

In a full year the paid holiday entitlement is 20 days excluding public holidays. The business will be closed for set days over the Christmas period and employees will be given this period as additional holiday.

Supermax Healthcare Ltd supports the principle of Equality and Diversity in employment wholeheartedly and opposes all forms of unlawful or unfair discrimination on the grounds of age, disability, sex, gender reassignment, sexual orientation, pregnancy and maternity, race, religion or belief and marriage and civil partnerships. We believe that it is in the company's best interests and those of all who work in it, to ensure that the human resources, talents and skills available throughout the community are considered when employment opportunities arise. If you have a disability or special need that requires support or adjustments to working or interview arrangements, please let us know.