REMOTE DIAGNOSTIC TECHNOLOGIES LTD

Staff Job Description

JOB TITLE: **QUALITY ENGINEER**

DEPARTMENT: **QUALITY DEPARTMENT** **EFFECTIVE DATE:**

SUMMARY OF JOB:

The Quality Engineer reports to the QSM to perform the activities necessary to provide support for RDT's activities (pre-dominantly with the production suppliers but also in the areas of R&D, admin, sales etc.) in line with our quality management system.

The QE will provide quality resource to the QSM for all quality activities. In particular the QE will:

- Provide support in the management of customer complaints
- Support and perform Corrective/Preventive Actions (CAPA) in the form of documenting and manage production/supplier non-compliances and customers returns
- Prepare information on performance of quality system for review by QSM, with recommendations of any changes required as a basis for improvement of the quality system
- Provide quality input on the day-to-day operation of the quality management system and taking action to correct problems arising from audits, complaints, and other sources of nonconformities, and where appropriate identify opportunities for correcting & preventing occurrence of such problems
- Provide quality input into new product development activities and new manufacturing activities
- Support the calibration of test, R&D and manufacturing equipment
- Prepare, review and issue procedures, instructions, and other quality documentation required by the quality system
- Assess systems to identify deficiencies and participate in resolution of issues found

The QE is required to otherwise offer general advice and assistance to the technical team in quality matters relating to the design, manufacture, suppliers and distribution of medical devices.

Job activities will be allocated by the line manager.

PRIME RESPONSIBILITIES:

Providing support to the QSM in the management of suppliers:

- Support for all returns, complaints, non-conformances and any other post-market issues
- Performing necessary quality activities (in conjunction with suppliers as required) to establish and document root-causes for identified non-conformances/issues
- In conjunction with the technical team to identify appropriate corrective changes and to implement those changes into production
- Working with Production & QSM to analyse returns and nonconforming product data to provide trending analysis on quality issues and performance metrics

- Working with different suppliers to implement quality tools to maximize the quality in products
- Solving the problems that occur due to quality and delay of products from suppliers
- Taking extra initiatives to encourage other suppliers to provide quality products at reasonable rate
- In the execution of the items above, provide support on quality matters to Production and the QSM with suppliers. This may involve managing some suppliers directly
- Where issues with problem suppliers cannot be resolved to work with the support of other team members to identify, evaluate and select new more effective suppliers
- Assist management with development of Quality Program Plan(s) and subsequent revisions
- Investigate product quality problems, determine root cause, gather and analyze data and implement corrective action to reduce or eliminate cause
- Assist in the development of quality system processes, i.e., records management and document control, control of electronic data, software development and control, etc.
- Support the current production activities in quality issues and to support the transition of new products into production. This will include:

    - Electronic and mechanical sub-systems, supplier liaison, supporting the validation of production processes etc.
    - Managing existing and new test equipment
    - Management of calibration of test equipment and the resolution of issues with calibration of test equipment

- Review and comment on drawings, calculations, specifications and other design inputs/outputs
- Provide support in developing inspection plans, First Article Inspection, In-Process and Final Product Inspection, Sampling Plans, inspection and acceptance criteria and Design Validation Testing
- Support operations and service department with NCR issues
- Provide input for design-for-quality issues
- Perform internal audits to assess compliance to Standards and to the internal Quality System, including investigation, presentation of observations and findings, and reporting.
- Apply sound systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving quality issues
- Perform supplier audits and qualifications
- Participate in the improvement of the manufacturing process for existing products. Review and approve work instructions, inspection documents, Bills of Material and drawings
- Maintain monthly metrics in preparation for management review
- Help facilitate continuous improvement and learning across all functional areas through training and communication of quality initiatives
- Perform work operations as per ISO and safety guidelines
- Assist in the development and delivery of specific Quality training

QUALIFICATIONS/EXPERIENCE:

Essential

- An HND or relevant degree in an engineering/technical discipline or equivalent
- Experience (>5 years) in either quality engineering of whole/finished electronic devices (with a degree of software content would be an advantage)
- Experience of electronic devices manufacturing
- Experience in managing supplier quality and performance perspective i.e. providing quality objectives to supplier and ensuring they deliver as specified

- Experience in fault finding/investigation, to establish and document root-causes for identified non-conformances/issues and finally to identify appropriate corrective changes and to implement those changes.
- The job will require an aptitude for working with suppliers and occasional national or international travel.
- Experience of working within an organisation operating an engineering quality system and meeting regulatory requirements.
- Hands-on experience of working to and implementing procedural changes to better meet the requirements of ISO9001/13485
- Good written English and attention to detail for written reports.
- PC literate

Desirable

- Experience in a quality engineering capacity for medical devices would be an advantage.
- Experience and understanding of FDA requirements (CFR 820) would be an advantage

Interpersonal Skills

- Strong interpersonal, communication, attention to detail and “self-starter” skills
- Ability to work as a part of a team, or individually while using own initiative
- First-class analytical and problem-solving skills with a dedication to maintaining high quality standards

LOCATION:

- Office based with occasional travel in the UK and occasional international travel.

This is an outline job description, and cannot cover the many detailed aspects inherent in the job. Jobholders will be expected to undertake similar or related duties and responsibilities to those listed. Where there is a significant change in the role or responsibilities, the job can be submitted for re-evaluation.

JOBHOLDER’S SIGNATURE: DATE:

LINE MANAGER’S SIGNATURE: DATE: