Job Description
Quality Manager

Reporting to

Chief Executive Officer

Summary of Key Responsibilities and Role

The Quality Manager will report to the Chief Executive Officer and will be based in the Coventry offices of Quantum Imaging. The role will be initially part time with a nominal 24 hours per week with the potential to increase this over time. They will have management responsibility for the maintenance and development of the company quality policy and adherence to ISO13485 and other appropriate standards as necessary. In addition the role will have oversight of Health and Safety for the facility.

The post holder will be responsible for the management, maintenance and continuous improvement of the ISO13485 Quality System Including controlled documents, procedures, forms and work instructions. This will involve the current compliance and continual challenge of assumptions and systems. In addition the individual will be the principle point of contact for competent authorities in relation to the Quality System and will manage the provision of a safe work environment.

Principle Responsibilities

- Own, challenge and continuously improve the existing Quality System.
- Ensure all documents and procedures are in place and kept current and relevant to the Quantum Imaging quality scope, i.e. design development and manufacture of medical devices.
- Be the management representative for all audits and manage the company Quality Management System (currently ISO 13485) and any other accreditations required, ensuring compliance with regulatory requirements and workmanship standards.
- Oversee the Corrective and Preventive action process, coordinating CAR root causes and corrective actions for both in-house and customer returns (RMA) and complaints, with follow up checks to verify implementation.
- Management of supplied material quality issues. Working with suppliers to ensure issues are effectively resolved and investigations are fully documented.
- Instigate and implement effective corrective and preventative actions (CAPA).
- Gather non-conformance data and document appropriately.
- Where appropriate, promote and drive the use of global best practice quality assurance both with the company and with external suppliers.
- Conduct both field based and desk based supplier audits as required.
- Own quality for the supply chain and manufacture and ensure that processes, practices and records are effective to ensure the end quality of our products is to specification.
- Ensure facility and all staff working in and external to the facility comply with current Health and Safety legislation.
- Be proactive to ensure changes to the relevant standards are adopted in a timely manner.
Required Skills and or qualifications

- A level of education appropriate to the role.
- Significant experience of internal and external audit essential and having acted as lead auditor qualification would be an advantage.
- Quality management expertise ideally from a production engineering background earlier in career.
- A strong electro-mechanical engineering and manufacturing background.
- Impartial and objective decision maker.
- Knowledge of and experience of working to electronic construction standards such as IPC - 610.
- Must have a "can do" attitude and be comfortable working in a small flexible and dynamic team.
- Be comfortable challenging staff at all levels including senior management on Quality Policies and systems and interacting with notified bodies.
- A working understanding of Microsoft Office suite.
- Must have a current and valid UK / European driving license.
- Must be available to travel nationally and where applicable internationally to conduct supplier audits.

Job Description received and acknowledged:

Name: ..........................................................

Date: ..........................................................

Signature: .....................................................