JOB DESCRIPTION

Job Title: Quality Manager

Reporting To: Clinical Director/CEO

Department: Quality **Location:** Swavesey

Position Summary:

The Quality Manager is responsible for, owns and drives quality management for the Company. Incorporating the full product lifecycle and business processes. The Quality Manager leads from the front instilling quality through the team. Working closely with the engineering, product and outsourced manufacturing teams the Quality Manager will ensure quality is intrinsic at every stage, using quality principles and tools to develop and optimize quality systems, product designs and manufacturing processes. You will independently determine and develop approaches to solutions and work on problems of diverse scope where analysis of data requires evaluation of identifiable factors and develop solutions for the same.

Main Responsibilities:

- Ownership of quality related activities within the business.
- Establish and lead the Quality Management of New Product integration.
- Create and drive the use of standard quality processes, performance and practices, implementing changes to processes and systems to enhance compliance and usability.
- Keep the appropriate teams informed of the quality status of all projects in advance of Stage Gates.
- Manage, review and approve all quality documents, procedures, specifications, non-conformance/events, protocols, reports, technical memos and change controls.
- Manage and communicate issues between appropriate stakeholders i.e. Logistics, Engineering, Technical Support, Regulatory Affairs, etc.
- Lead regulatory visits, corporate audits and vendor audits and provide follow up on regulatory commitments.
- Ensure all existing approvals are maintained, where necessary, submit compliance documents, e.g. for the FDA and CE approvals.
- Ensure the need for new approvals for design, development and marketing is fully assessed.
- Ensure personal and company compliance with all necessary regulations, policies, and procedures for health, safety, and environmental compliance.
- Mentor the development team in its compliance with quality processes.
- Produce development project Quality Plans.

- Lead the migration of all software development processes to an agile mode while ensuring regulatory compliance.
- Lead the quality aspects of design reviews and pre-validation assessments to ensure the safe and environmentally sound start-up of new processes.
- Lead Escalation of Delays, Rejections and Non-Compliance to Standards.
- Lead Quality portion of Design Review and Stage Gates.
- Manage, conduct, and own quality risk assessment activities.
- Ensure Device quality assurance meets project timelines.
- Collaborate with all stakeholders and business partners to meet goals and objectives.
- Lead and manage the other member(s) of the Quality team via the setting of objectives and a strong focus on performance management and personal development in line with the needs of the business.
- Maintain a regular audit schedule.
- Be responsible for post market surveillance and customer satisfaction surveys, including ensuring the business is informed of any regulatory updates.

Minimum Qualifications/ Experience Required:

- Proven related experience in the medical device, pharmaceutical and/or biopharmaceutical industry.
- Knowledge of device design, process engineering, and/or bioprocessing manufacturing and test processes in a Biotech, Pharma Manufacturing, or Device manufacturing environment is preferred.
- Knowledge of pharmaceutical clinical trial software regulatory requirements including but not limited to 21 CFR Part 11 & GCP
- Proven experience in implementing, managing and maintaining ISO 13485, ISO 9001 and EN 60601
- Knowledge of quality standards involved in design, development manufacturing and marketing of medical and non-medical devices and software, including but not limited to FDA, ISO 13485, IS0 9001 and EN 623054
- A background in at least one of software or hardware development.
- Participation in cross department.

Key Competencies/Attributes Required:

- Analytical
- Strong technical and process knowledge
- High levels of integrity
- Attention to detail
- Self driven