Employee Position Description

ST-080

Job Title: Quality Manager

Department: Quality

Reports To: CEO

Summary of Position
Lead the Quality Team, providing a full range of quality and regulatory functions to the business. A member of the Senior Management Team.

Essential Duties and Responsibilities

- Driving quality objectives, specifically those needed to meet requirements for the product, ensuring that they are managed and delivered by relevant functions within the business.
- Providing the quality & regulatory support to ensure that the required production, quality and regulatory standards are achieved.
- Act as a key member of the Senior Managment Team, providing strategic input on all areas of the business.
- Evaluating and reporting on the performance of the Quality Management System and the needs for improvement to Senior Management.
- Communication with the Notified Body and US representatives on Quality and Regulatory issues.
- Promoting the awareness of regulatory and customer requirements throughout the organization, from suppliers through to senior management.
- Review the performance of the organization's Quality System to ensure its continuing suitability, adequacy, and effectiveness.
- Involvement in activities inter---departmentally, to include a risk---based approach and completion of tasks towards quality improvement.
- Encourage the shaping of respective departments into one effective team, while still maintaining the highest quality standards.
- Ensures project deadlines and performance standards are established and met.
- Ensure that QMS within the company is maintained at the highest possible levels.
- Batch review and sign off. Control of all batch documentation
- Issuing of Certificate of Analysis (CoA's).
- Set up and administer change control and customer complaints.
- Establish and maintain relevant standards for in-house IVD assay with production/ technical staff.
- Drive projects relating to quality improvement initiatives.
- Implement meaningful and measurable key performance indicators to monitor the Quality Management System
- Develop a continuous improvement process for the business.

- Oversee the Quality management system and supporting Technical Files, SOPs, standards, methods, and procedures both for inspecting, testing and evaluating precision, accuracy and reliability of the Company's products.
- Responsible for quality issues around product design, development and production transfer.
- Maintain the smooth running of the organization's operations
- Provide and co---ordinate QA input during packaging activities.
- Final product documentation approval

Regulatory Affairs

- Lead preparations for internal and third party audits, preparing audit reports and responses to observations, providing recommended conclusions and actions with implementation.
- Preparation and review of regulatory submissions required for product approval.
- Author, coordinate the Regulatory/QA review and approval of technical documents and reports, quality agreements, validation documentation, protocols and Master Batch Records Provide advice and guidance on regulatory compliance and risk issues
- Ensure that all compliance requirements are met
- Advises on risk assessment and risk management strategies for projects.
- Maintain, communicate and enable a strong understanding of current FDA and EU regulatory requirements company---wide.
- Keep management informed of significant regulatory changes that may impact the business

Internal/external audits

- Maintain and undertake reviews and internal audits of quality related processes
- Manage external audit requirements by international quality organisations and customers' quality representatives. Represent the company at audits.
- Participate in FDA inspection preparedness program
- Control and prepare Import/export licenses as required Other tasks and responsibilities as requested.

Carry out other duties as required.

Supervisory Responsibilities
Act as a coach and mentor. Lead by example. Manage, develop and co-ordinate the activities of the staff in area of responsibility, ensuring adherence to policies and procedures.

Authorities for Position
Follow the principles in the Quality Manual and all associated documentation within the QMS system. Authorities as defined in the Company Policies.

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Competency and Qualifications Required for Position
• A Bachelor's Degree in Science or equivalent. • Previous experience in a Production/Biotech/Medical Device industry. • Experience in Quality Management Systems and international accreditation including ISO 13485, FDA QSR and cGMP • Solid internal and external auditing experience. • Strong Quality Management/Document Control background. • Good understanding of risk assessment, HACCP, RMP, FSP, cGMP. • An analytical approach and a background which allows for a structured and logical approach to data management and problem solving. • The ability to effectively prioritise within an active, fast moving bioprocess manufacturing environment. • A passion for promoting and enhancing a company quality culture, created through generation of buy-in by others across all parts of the organization. • High level of accuracy and attention to details. • A positive attitude and passion for process improvement. • Computer literacy.