Job Description for the position of Head of Quality Assurance and Regulatory Affairs

Location: Bray, Co. Wicklow, Ireland

Company Overview:

Trinity Biotech specialises in the development, manufacture and marketing of diagnostic test kits. Trinity Biotech's continued success is based on the fact that as a company it consistently achieves standards of excellence in the quality of all it does. Since its formation in 1992, Trinity Biotech has actively pursued the aim of becoming a leading player in the international diagnostics industry. A combination of strong organic growth and a progressive acquisition-led strategy has seen the company assemble an impressive portfolio of over 400 products to date.

Quoted on the NASDAQ exchange, and with facilities in Ireland, Sweden and the United States, Trinity Biotech sells its products in more than 80 countries. It reaches this worldwide market by combining the skills of its own sales force with a network of international distributors and strategic partners.

Overview of the position of Head of Quality Assurance & Regulatory Affairs:

Reporting to the Head of Irish Operations, the Head of QA and RA is responsible for providing guidance on all aspects of quality within a cross functional team thus ensuring product quality and customer satisfaction. The Head of QA and RA will also be responsible for overseeing and directing Trinity Biotechs subcontracted manufacturing.

The Head of Quality Assurance and Regulatory Affairs is responsible for:

- Management of Quality personnel within the Quality department. The Quality department is responsible for the following functions: Regulatory Affairs, Quality Engineering, Quality Assurance, Final Batch Release and Incoming inspection, Documentation Control, Validation and Production Line Clearance.
- Key member of the Operations Management Team and Corporate Quality Team.
- ISO9001 Management representative (ISO9000, 4.1.2.3, ISO 9001, 5.5.2), ISO 13485.
- Keep up to date of current Quality Standards and Regulations impacting the IVD industry.
- Control of the Quality Manual including preparation, revision and execution.
- Responsible for organising Management Review and compiling and reporting on the performance of the quality system.
- Ensuring that all customer specific quality requirements are compiled with following contract review.
- Management of the product review and release system and signature on Certificates of Conformity.
- Management of Change Control and Document Control Systems.
- Issuing, control and filing of all batch related documentation.
- Responsible for final sign-off on all product labels, package inserts and Marketing Material.
- The organisation of product and facility inspection, preparation of procedures and instructions including certification assessment and surveillance audits, FDA inspections, other regulatory inspections and supplier audits.
- Ensuring that validations are performed on equipment, processes and software used in manufacturing and testing of product.

- The Management of non-conformance and corrective and preventative action systems including the control of further processing and delivery of non-conforming product until any deficiencies or unsatisfactory conditions have been corrected.
- Responsible for coordination of issuing Product Safety Notifications or Product Recalls as well as Medical Device Reporting (MDR) with the Vice President of Regulatory Affairs.
- Ensure latest updates of regulatory requirements are implemented and available for use and communicated to other facilities in the Trinity
- Ensuring Compliance with worldwide regulations/ regulatory submissions.
- Key participant in design control.
- Assist with FDA regulatory submissions with the Vice President of Regulatory Affairs.
- To communicate the awareness of customer requirements throughout the organisation and to champion Quality and continuous improvement initiatives.
- To liase with external parties on matters of the quality management system.
- Ensure that Health and Safety procedures are adhered to at all times and that Trinity Biotech ensures that at a minimum all legislative requirements are adhered to.

Education and Experience:

- Primary degree qualification in a science, engineering or business discipline or equivalent in terms of relevant operational experience
- 5-7 years + industrial experience, three years or more in the IVD industry or similar industry is required.
- Must have experience in project management of change programs
- Firsthand experience of audits by regulatory authorities.
- Experience in hosting and leading FDA and other regulatory authority audits, would be an advantage.
- Extensive experience of developing and delivering effective training on Quality Systems and Processes
- Demonstrated track record and success in team building skills
- Demonstrated experience of people management

Skills and Behaviours:

The Head of QA and RA should demonstrate the following skills and behaviours:

- A logical and planned approach to all tasks
- An excellent communication skills, (both written and verbal), excellent interpersonal and presentation skills and be team focused.
- An in-depth knowledge of International Standards, GLP, and GMP
- Ability to manage complex projects involving multiple functions
- Ability to gain consensus on key quality/operational decisions.
- Strong analysis/problem solving skills
- Strong attention to detail/quality focus
- Balanced cost/quality/customer focus
- Willingness and ability to collaborate with and influence other groups in a positive, team-based environment. Must also be able to hold others to account as required.
- Work with a sense of urgency and have the ability to be impartial and objective.
- Be an active learner and developer of self and others with excellent organisational skills.

Please contact Denise.cross@trinitybiotech.com for further information.