

Job Title: Quality Officer

Reporting to: Quality Manager

The Quality Officer is responsible for Quality Management system activities within the company.

Competency Requirement:

- 1) Science-based and/or quality-based background
- 2) At least 2 years industrial or similar experience
- 3) Ability to develop and improve quality management systems
- 4) Ability to resolve technical and quality problems
- 5) Proficient in MS Word, Excel and Outlook

Responsibilities and Duties:

- 1) To develop, maintain and continuously improve the quality management system.
- 2) To provide technical support to the sales team and customers.
- 3) To provide technical support to the management team for the introduction of new products.
- 4) To oversee that all customer complaints are investigated and reported and that suitable countermeasures are implemented.
- 5) Support the daily tasks and the supporting documentation and processes associated with the quality system, including but not limited to RGAs, CAPAs, deviations, and customer complaints
- 6) Investigate, diagnose, and facilitate customer complaints and recommend corrective actions to Management
- 7) Facilitate product and process testing and validations that support the Quality Management System
- 8) Learn and maintain competency in Document Control processes to be able to coordinate document change requests.
- 9) Recognize and handle product and process nonconformities
- 10) Provide monthly reporting on the quality metrics
- 11) Verify logs, databases, and other quality records and data to track and flag quality concerns and improvements to be reviewed by Management
- 12) Oversee that the quality of purchased products and raw materials is sufficient to meet customer requirements (secondary responsibility).
- 13) Oversee the operation of incoming product assessment and to ensure that all test procedures are in-place and that test equipment is suitably calibrated (secondary responsibility).
- 14) To carry out audits (internal and supplier) in compliance with ISO 13485.
- 15) To provide GMP and QMS training to the team.
- 16) To carry out additional tasks under the guidance and direction of the Quality Manager where required

Authority:

- 1) To liaise with suppliers and customers to resolve quality and technical problems.
- 2) To pass and Fail any product deemed to be unacceptable.
- 3) To make any necessary changes to the Quality Management System.

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