
Quality Engineer

Position Summary

Reporting to the Quality & EHS Manager this position will be responsible for providing quality engineering support across multiple functions within Cambus Medical.

Duties and Responsibilities

- Ensure that Production operations within assigned area are completed in accordance with the requirements of the Cambus Medical Quality System.
- Ensure all customer requirements are identified, documented, understood and met.
- Document manufacturing procedures, CHR's, purchasing specifications, inspection procedures and standards etc... as required. Review and approve all updates to same.
- Ensure all processes are maintained in a validated state. Assess all changes for their impact on validations, product quality and the customer.
- Oversee the execution of validation activity, FMEA's, OQ, PQ as required.
- Ensure all product/process quality issues that arise, including customer complaints, are effectively resolved in a timely manner using the Cambus Medical CAPA system.
- Promote the need for continuous improvement within assigned area.
- Utilise, lead and mentor team members on structured problem-solving methods.
- Perform internal audits as per agreed schedule and assist with preparations for external audits.
- Keep your skills current and be conversant with the latest developments in quality and regulatory systems which are relevant to the Company's business.
- Participate in improvement activities, including Kaizen events, ensuring that quality requirements are followed during the change implementation process.
- Take on other duties which the Company may assign you from time to time.

Requirements

- Must have a third level qualification in Engineering/Quality/Science.
- A minimum of 5 years' experience in a regulated manufacturing environment.
- Knowledge and experience of process validations.
- Proven to be self-directed, self-motivated and able to prioritize workload.
- Must possess excellent verbal & written communication skills, which include but are not limited to presentation, organizational and management skills
- Must have a working knowledge of statistics, SPC, and ideally the use of Minitab
- Knowledge of GMP & Regulatory requirements.
- Strong understanding of structured problem-solving techniques.
- A positive attitude in dealing with and mentoring people.
- An aptitude and drive for Continuous Improvement.
- IT skills – Microsoft Office, Minitab, ERP Systems