

Quality Engineer I

Purpose

This role will form part of the Quality Assurance Team. The primary objective of the role is to ensure products are manufactured in accordance with customer requirements and the requirements of the Quality Management System.

Duties and Responsibilities

- Ensure all customer requirements are identified and clearly documented in Cambus Medical manufacturing documentation. This documentation includes CHR's, Work Instructions, Visual Standards, Purchasing Specifications, FMEA's etc.
- Document manufacturing procedures, CHR's, purchasing specifications, visual standards etc. Review and approve all updates to same.
- Investigate product/process quality issues that arise, including customer complaints. Ensure they are effectively resolved in a timely manner using the Cambus Medical CAPA system.
- Assess all product and manufacturing related changes, deviations and reworks, for their impact on validations, product quality and the customer.
- Review, control and disposition non-conforming product in accordance with the Cambus Medical NCR system.
- Make product dispositions as and when required. Update documentation such as specifications and visual standards to better define the quality characteristic being dispositioned.
- Prepare process data such as yield, output rates, No. of NCR's etc. and use this data to identify opportunities for improvement. Implement improvements on an ongoing basis.
- Perform internal audits as per agreed schedule and assist with preparations for external audits.
- Write validation protocols, reports and test reports as required.
- Perform First Article Inspections as required.
- To take on other duties which the Company may assign you from time to time. These 'other duties' will be agreed with Management prior to any assignment.

Requirements

- Degree / Diploma qualification in Engineering, Science and/or Quality or relevant experience in a quality assurance role within the Medical Device Industry.
- A minimum of 3 years experience in a similar role.
- Excellent attention to detail.
- Ability to use problem solving tools (A3, PDCA, 5 Why's, Fishbone etc.)
- Good communication skills both verbal and written.
- A positive attitude in dealing with people.
- Experience working with Data Analysis Software (i.e. MiniTab) an advantage.
- Understanding of lean principles. Lean green belt an advantage.
- Ability to learn and adapt to various situations.