Senior Quality Engineer

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. This role will take the lead in implementing an improving the quality assurance function throughout the business.

Duties and Responsibilities

- Be the leader of Quality within assigned area. Act as the designate for the Quality Manager.
- Continuously promote quality and customer satisfaction in everything that the company does.
- Ensure the Quality System is effective for the products being manufactured and fully compliant with customer and regulatory requirements.
- Ensure all customer requirements are identified, clearly documented in Cambus Medical manufacturing documentation and effectively implemented.
- Provide expert quality input into validations, change management, problem solving and product disposition activities.
- Work with customers and suppliers on quality related issues and new product introduction projects. Ensure all dealings are professional and good relationships are maintained at all times.
- 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.
- Ensure effective change control practices are implemented.
- Lead quality related projects ensuring that they are delivered on time and within budget.
- Be part of project teams. Deliver on commits to schedule and budget.
- Act as a Lead Quality Auditor. Perform Supplier Quality Audits. Act as a guide during customer and regulatory audits.
- Be an expert on-site for statistical analysis and problem solving.
- Ensure that continuous improvements are planned and implemented on an ongoing basis.
- Manage a team of Quality Engineers and Technicians. Coach and mentor the team.
- 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 7 years' experience in a similar role.
- Proven track record in leading quality within a medical device manufacturing company.
- Ability to manage quality related projects.
- Proven track record in people management. Must be able to manage a team of up to 8 staff.
- Excellent attention to detail.
- Thorough knowledge of applicable regulatory requirements (ISO 13485, FDA etc.)
- Proven track record in problem solving. 6 sigma qualification (Green Belt of higher).
- Understanding of lean principles. Lean green belt an advantage.
- Excellent communication skills both verbal and written.
- A positive attitude in dealing with people.
- Ability to learn and adapt to various situations.
- Must be able to work under own initiative, with minimum supervision.

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