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## Quality Manager

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The Quality Manager is a key senior role and is a member of the site management team. This role will continuously promote quality and customer satisfaction and will lead the company's continuous improvement program. This role will also ensure that the company complies with all applicable quality system requirements and regulations.

### **Duties and Responsibilities**

- Be the leader of quality and continuous improvement within the company. Continuously promote quality and customer satisfaction in everything that the company does.
- Ensure that customer requirements are understood and achieved for the lifecycle of the product. 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.
- Develop and implement effective and efficient quality management strategies, policies and procedures. Ensure that the Quality Management system is effective and fully compliant with customer, regulatory, legislative and business requirements.
- Lead the company continuous improvement program, utilising lean and six sigma principles, tools and techniques. Ensure that continuous improvements to product quality and processes are planned and implemented.
- Provide expert quality assurance input into problem solving, change management, validations and product disposition activities.
- Ensure that problems are effectively solved using systematic problem solving methodologies. Coach and mentor staff in problem solving.
- Fulfil the role of management representative for the Quality Management system.
- Ensure supplier quality is effectively managed.
- Manage and develop the Quality team which will consist of Quality and Continuous Improvement Engineers and Technicians. Manage the quality function within agreed budget.
- Lead quality related projects ensuring that they are delivered on time and within budget.
- Prepare for and manage customer and regulatory audits (Quality & Environmental).
- To take on other duties which the Company may assign you from time to time.

### **Requirements**

- Degree qualification in Quality, Engineering, Science or relevant experience in a quality assurance role within the Medical Device Industry.
- Proven track record in leading the quality function within a medical device manufacturing company.
- Thorough knowledge of quality management systems and associated regulatory requirements (ISO 13485, FDA etc.).
- Detailed knowledge and understanding of statistical analysis (including Minitab).
- Must be able to communicate at all levels of the organisation and with customers, suppliers and regulatory agencies.
- Good interpersonal skills, team player, with a positive attitude in dealing with people.
- Must be innovative and be driven to implement change to systems and procedures.
- Excellent analytical skills. Ability to define problems, collect data, establish facts, and draw valid conclusions.