DEVICE TECHNOLOGIES

JOB DESCRIPTION

Job Title:	Quality Assurance Specialist – Process

Department/ Business Unit:	RAQA	**Reports to:**	Senior Quality Assurance Manager

Job Purpose

- To effectively administrate the Quality Management System policies and processes for the company
- Collaborate with other functional teams to support and facilitate process improvement
- To conduct internal and supplier audits, as required in accordance with the established procedures
- To support Senior QA Manager, internal and external customers to achieve and maintain ISO 9001 certification

Reporting/Working Relationships

- Reports to: Senior Quality Assurance Manager

Key Responsibilities

- Supports the Senior Quality Manager with the day-to-day quality operations with a focus on executing and maintaining quality assurance procedures.
- Reviews quality documents, as required to support the ongoing growth and development of the quality management system.
- Lead RAQA management with non-conformances, process improvements and support other functions as required
- Monitor, analyze and report on Quality Improvement Register (QIR) on monthly basis
- Ensure that non-conformities are recorded and the resultant actions are effective through root cause analysis and stakeholder engagement and are completed in a timely manner;
- Identify and execute opportunities for continuous improvement;
- Assist Senior QA Manager to prepare the Quality Management Review of the quality management system and ensure resulting actions are resolved;
- Administer Quality Management System for the business and relevant entities;
- Manage quality documentation to meet organization’s needs in compliance with ISO 9001 requirements;
- Perform internal audits as a Lead Auditor supporting the internal audit program and other audit requirements;

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- Prepares for audits by researching materials, standards, policies and procedures to formulate a plan of action;
- Promote awareness and understanding of the quality management system;
- Design training resources and provide training for quality related processes;

Quality and Safety Requirements and Responsibilities

- Comply with Quality System requirements;
- Take reasonable care for your own health and safety and do not negatively affect the health and safety of others. Comply with any instructions and follow any policy, procedure or work instruction relating to health and safety at the workplace that has been notified to you;
- To ensure compliance with applicable legislation, customer requirements and given the exposure risk to the business, it is a requirement of this role that you maintain any appropriate vaccinations and background checks as appropriate.
- Conduct all activities and duties as part of this role in full accordance with company policies, procedures, and values.

Selection Criteria

Qualifications, Skills and Experience

Essential

- Understanding of Device Technologies policies and procedures including any vaccination and background checks in line with your role and responsibilities.
- 3+ years' experience in medical device or related industry
- Must possess significant level of knowledge of the ISO standards (ISO 9001, ISO 13485, ISO 19011)
- Strong experience with NCR and CAPA management including root cause analysis
- Strong background in internal or supplier auditing
- Auditing qualifications - Internal auditor or Lead Auditor certification
- Experience with QMS within medical device industry
- Great communication skills
- Ability to work well independently and as part of a team

Desirable

- Tertiary qualification in related field or equivalent work experience
- Familiarity with supplier management process

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- Experience with developing and delivering training modules