DEVICE TECHNOLOGIES

JOB DESCRIPTION

Job Title:	Senior Regulatory Affairs Associate (SRAA)

Department/ Business Unit:	RAQA	**Reports to:**	Regulatory Affairs Manager

Job Purpose

- To perform regulatory functions and ensure ongoing regulatory compliance for new and existing products within the Device Technologies product offering
- To support regulatory department management functions
- To provide leadership to the Pre-market team and back up for other RA roles as required

Reporting/Working Relationships

- Reports to the Regulatory Affairs Manager

Key Responsibilities

- Collaborate with HQR, RA Management and Business Management to ensure effective and timely regulatory applications in the target region
- Assess requirements for allocated product or product range to ensure complete regulatory compliance in the target region
- Liaise with both local and overseas suppliers/manufacturers on regulatory issues and to obtain required documentation for regulatory compliance and new applications
- Prepare and lodge regulatory applications for Australia, New Zealand, and other relevant regions
- Submission authority for TGA manufacturer's evidence and medical device applications up to Class IIb;
- Develop and maintain excellent working relationships with relevant regulatory bodies including various government departments;
- Undertake and assist others with more complex applications such as Class III, Medicines, AQIS, PVs, Chemicals, Prostheses List, RCM etc.;
- Maintain all regulatory technical files, databases, spreadsheets and internal registers for allocated product ranges
- Ensure accuracy and currency of data held on all databases (SAP, the Hub, etc.) for allocated product ranges
- Collaborate with Business Management and Sales teams to provide relevant regulatory information as required for tenders, quotes, customer requirements, product launches, principal meetings etc.;
- Provide training, coaching and leadership of less experienced team members with the intention to increase the general knowledge and effectiveness of the regulatory team
- Identify areas of development for the Pre-Market team and facilitate upskilling of individuals and/or the team in collaboration with RA management

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- Investigate and resolve quarantined non-conforming product according to internal quality procedures
- Review and process internal new product requests according to internal quality procedures
- Review marketing materials according to internal quality procedures
- Authority for other RAQA department approvals including releasing product from Quarantine and marketing materials;
- Assist with all mandatory reporting requirements for recalls, adverse incidents and other issues as directed;
- Undertake projects involving collaboration with Pre-market, Post-market and/or QA as needed e.g. systems development, auditing, or reporting requirements;
- Promote the core values and behavioral code of Device Technologies
- Assist HQR and RA Management with other functions as required;
- RAQA with back up when other team members are on leave, or as otherwise required.

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.
- Understand and adhere with Principals' applicable compliance, code of conduct policies and procedures;
- Understand and adhere with MTAA &/or MTNZ Code of Conduct.

Selection Criteria

Essential

- Understanding of Device Technologies policies and procedures including any vaccination and background checks in line with your role and responsibilities.
- Knowledge of, and at least 3-year experience in, the Australian medical device regulatory environment.

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- Excellent attention to detail
- Excellent understanding of medical terminology
- Excellent computer skills (Word, Excel, SharePoint);
- Excellent organisational skills;
- Excellent communication skills, both written and oral English;
- Ability to work well under pressure;
- Ability to work well independently and as part of a team;

Desirable

- Tertiary qualification in relevant field (generally Science, Biomedical Engineering etc.);
- Experience using SAP and Adobe Professional
- Demonstrated leadership capabilities