m|devices
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Position:	Quality Assurance / Regulatory Affairs Associate
Location:	Villawood
Hours:	Monday-Friday (9.00am-5.00pm)
Start Date:	ASAP

The m|devices team is seeking a proactive individual to join us in a combined Quality Assurance and Regulatory Affairs role to ensure continued compliance to mandatory standards for medical devices design and manufacturing.

Responsibilities include but are not limited to:

- Contributing to the development, implementation and maintenance of the quality assurance program and related policies and procedures to ensure compliance
- Coordinate preparation, review and issue of Standard Operating Procedures (SOPs) to support quality systems
- Review and approve validation documentation to ensure compliance with Regulatory requirements
- Internal audits
- Ensuring that all products/batches are released in compliance with internal Quality Standards, Quality Agreements, Registered details and Regulatory GMP or compliance requirements
- Review, approve and support Change Controls and CAPAs
- Liaise with Supplier and Customer Quality Representatives with regards to batch release and quality issues
- Identify and closeout any compliance related issues
- Co-ordinate product complaints process
- Actively participate as a compliance and quality representative on projects to ensure appropriate governance on for all activities
- Generate and maintain relevant documentation (inclusive but not limited to SOPs, Forms, Product Quality Reviews, Audit Reports, Manufacturing

Instructions, Packaging Instructions, Product Specifications and Analytical methods) required for the effective management of compliance

This position requires someone who has the following attributes:

- Minimum 3 years' experience in a similar role within medical device industry
- Previous Regulatory experience
- Supervisory / Management Experience
- Auditing background
- Critical thinking
- Attention to detail
- Excellent time management skills
- Excellent written and verbal communication
- Demonstrated ability to take initiative in problem solving and in exercising judgment
- Familiarity with ISO 9001 and/or 13485
- Proficient in Excel, Word and experience in ERP systems as well as exposure to, or experience with Quality Management System (QMS) software
- Experience liaising with the TGA or working knowledge of TGA regulations

Respond to: HR@mdevices.com.au