

## Regulatory Affairs and Quality Manager

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Company: i-Pharm Consulting

Location: Australia

Category: other-general

RA Manager, Regulatory Affairs Manager, RA & QA Manager Opportunity for an experienced Regulatory Affairs and Quality Manager to join an Australian owned medical device company. You will play a crucial role in ensuring the company and distribution partners maintain compliance with government legislation and guidelines, locally in Australia and globally. As an RA & QA Manager you will oversee ISO 9001; 2015 process, guaranteeing all standards are met. You'll collaborate closely with the product development team to identify and advise on regulatory requirements for new products, oversee artwork approvals, and collaborate with our international sales team to register products for overseas markets. Responsibilities: Identify, prepare and submit documentation to the relevant region regulatory bodies; including but not limited to the Therapeutic Goods Administration, FDA, EU and UK Rep. Provide regulatory support for medical, marketing and other corporate functions as required. Management government approval for medical devices. Maintain regulatory marketing and variation applications for Australia and New Zealand, the US and UK/European bodies. Oversee QMS including document control, to ensure compliance with ISO 9001 and other relevant standards. Management of the companies recall policies and procedures. Skills: Sc. in scientific or related discipline. 5+ year's experience within the medical device industry. Knowledge of FDA, TGA, EU medical device regulations. Apply direct now, or send your updated CV to Ben Byrne at [bbyrne@i-pharmconsulting.com](mailto:bbyrne@i-pharmconsulting.com) OR (02) 8310 5849

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