

## Manager Regulatory Affairs

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Company: Laborie Medical Technologies Corp

Location: Australia

Category: other-general

We believe that great healthcare is an essential safeguard of human dignity. At Laborie, we know the work we do matters – it's what fuels our motivation and contributes to our success. If you're ready to make a positive impact in the lives of patients across the globe, we'd like to meet you. We support and empower our employees to grow their careers in an environment that encourages a sense of belonging and a connection to doing good. We're not afraid to roll up our sleeves to make our goals a reality and work together to solve for our customers. We reward and recognize our employees based on our values of Aspire to Greatness, Respect All, Own It, Working Together, Persist with Passion. Who We're Looking For: The Manager Regulatory Affairs ensures compliance with applicable laws and regulations in the development, manufacturing, and marketing of Laborie Medical and its subsidiaries' products, and uses this knowledge to support pre-market and post-market activities and will work closely with Quality Assurance, Clinical Affairs, Sales and Marketing, Engineering, and Manufacturing for compliance to regulations. About the Role: Manage the daily operations of the Regulatory Affairs, including: Management of the Regulatory Affairs Specialists. Oversee and prepare domestic and international regulatory submissions. Prepare and review 510 (k) and PMAs and PMA supplements for new and current products. Provide guidance and oversight to team members related to regulatory compliance. Provide regulatory input to Laborie Medical design teams for the development of new products or procedures. Support inspections by FDA, notified body, and other regulatory agencies. Minimum Qualifications: Bachelor's Degree with at least 5-8 years of related Regulatory experience, mostly in medical devices. 3 years' experience in a Regulatory Affairs

leadership role preferred. Extensive knowledge of global medical device regulations and standards, such as, but not limited to FDA, MDD, EU MDR, Health Canada, Australia, Japan etc. Excellent oral and written communication skills. Strong ability to multitask and work in multi-disciplined teams. Why Laborie: Our Mission every day is to operate as a world-class specialist medical company making and advancing technologies that preserve and restore human dignity. We do that today by helping people with pelvic and gastrointestinal conditions live normal lives, and by helping mothers and babies have safe deliveries. Paid time off and paid volunteer time Medical, Dental, Vision and Flexible Spending Account Health Savings Account with Company Funded Contributions 401k Retirement Plan with Company Match Parental Leave and Adoption Services Health and Wellness Programs and Events Laborie provides equal employment opportunities and non-discrimination for all employees and qualified applicants without regard to a person's race, color, gender, age, religion, national origin, ancestry, disability, veteran status, genetic information, sexual orientation, or any characteristic protected under applicable law. Laborie is committed to providing access and reasonable accommodation in our services, activities, education, and employment for individuals with disabilities.

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