

Job Summary

Director/Manager of Regulatory Affairs

Salary:	Open	Location:	Camarillo, California
Employer:	Kinamed Inc	Type:	Full Time – Experienced
Sector:	Private Industry	Discipline:	Regulatory/Quality
Required Education:	4 Year Degree		

Employer Information

About Kinamed Inc

Kinamed is a small, privately-held medical device company with a seasoned management team and an experienced workforce. We are fully integrated, focusing on implantables and instruments for orthopaedics and neurosurgery, including sterile-packed implants, instruments, and disposables. Our devices are sold in 30+ countries throughout the world.

Job Description

The position is primarily responsible for interpreting and maintaining compliance with US FDA and ISO 13485 medical device regulations, as well as particular requirements of other international regulatory agencies, at all levels of the organization. It requires the application of practical experience and a technical knowledge base for developing, implementing and leading the regulatory and quality control systems within defined regulations in meeting strategic and day to day objectives. It requires both attention to detail and process considerations in execution of responsibilities. This position reports directly to the Company's President.

Requirements

- A bachelor's degree in a scientific or technical discipline with three (Manager) to six (Director) years of orthopedic industry experience in quality or regulatory affairs;
- Demonstrated knowledge of US FDA, ISO 13485, and MDD regulations, plus the quality/regulatory requirements of various foreign bodies such as PMDA, SFDA, TGA, etc;
- Hands-on experience with the preparation and submission of 510(k), Technical File, and other international registration dossiers;
- Self-motivated, self-directing, strong attention to detail and excellent time management skills;
- Strong interpersonal and management skills with the ability to communicate well, verbally and in writing;
- Multi-lingual skills are beneficial;
- RAC certification is beneficial.

<http://www.kinamed.com/corporate-info/employment>