

Career Paths



A Job Posting System for Employees of Davol Inc.

Department: Regulatory & Clinical Affairs **Posting Date:** 5/13/09
Job Title: Senior Manager/Director Regulatory & Clinical Affairs
Position Level: 13/14*

Summary of Position with General Responsibilities:

The Senior Manager/Director, Regulatory Affairs is responsible for the development and management of the regulatory affairs function through the recruiting, hiring, supervision, and advancement of regulatory affairs personnel in the support of Davol product development and overall business objectives.

Essential Job Functions:

- Recruit, manage, develop and mentor regulatory affairs professionals.
- Work with regulatory associates, determine submission and approval requirements and prepare regulatory submissions
- Monitor and submit applicable reports and responses to regulatory authorities and negotiate and interact with regulatory authorities during the development and review process to ensure submission approval.
- Assist in regulatory due diligence and acquisition transfer activities.
- Prepare and manage annual budgets.
- Manage and execute pre-approval compliance activities.
- Maintain annual licenses, registrations, listings and patent information.
- Review and approve labeling, advertising and promotional items to ensure compliance with regulations and company policy.
- Review publicly disseminated information to minimize regulatory exposure, review product claims and preserve confidentiality of applicable product information.
- Review and approve required reports, supplemental submissions and other postmarketing commitments to update and maintain product approvals and registrations.
- Provide regulatory input for and appropriate follow-up to inspections and audits.
- Develop, implement and manage appropriate SOPs and systems to track and manage product-associated events.
- Submit/review change controls to determine the level of change and consequent submission requirements.
- Provide training for stakeholders on current and new regulatory requirements to ensure company-wide compliance.
- Conduct technical meetings with regulatory advisory committees and government agencies.

Basic Qualifications:

- B.S. Science, Engineering, or other technical Degree or experience.
Professional certification (RAC) highly preferred.

- Knowledge of and experience (8-10 years) with regulatory submission for medical devices (IDE's, 510(k)'s, and PMA's, outside –US regions). Familiarity with drug/device combination products preferred.
- Must have demonstrated extensive working knowledge of the U.S.A. Federal Regulations for medical devices including those applicable to the import/export of devices.
- Must have demonstrated extensive working knowledge with the requirements for medical device registration/licensing in the EU, (Medical Device Directive), Japan, Canada, Australia, Latin America and Asia/Pacific.
- Knowledge of medical products quality system principles and practices.

Additional Desirable Qualifications Skills and Knowledge;

- Ability to work in a matrix/team environment with prior experience supervising regulatory affairs professionals.
- Solid skills in written and oral communications. Positive energy and enthusiasm to work in a multi-task environment.

Remarks:

Some travel required.

If you are interested in the above position and consider yourself qualified, apply on-line at www.jobs-cr Bard.icims.com. In conformance with the Davol Equal Employment Opportunity Policy, the above opening will be filled based on the applicant's ability, length of service and performance record.