



Director of Regulatory Affairs

Position Summary:

The Director of Regulatory Affairs is responsible for all aspects of the regulatory strategy related to medical and non-medical devices, environmental, safety, patents, trademarks, and technology licensing. The incumbent will be responsible for the execution of the regulatory strategy in compliance with the laws, external customer requirements, regulations and regulatory agencies associated with Rauland-Borg products for the USA & International markets.

Accountabilities:

- Responsible for coordination & preparation of regulatory submissions and strategies.
- Develop & maintain regulatory knowledge of US and international regulations.
- Manage the final product submissions and negotiate and communicate effectively with regulatory authorities to obtain timely product approvals.
- Analyze & communicate proposed, new or changing requirements for standards.
- Lead teams to develop strategies, programs and process to meet business objectives and ensure timely compliance with regulatory requirements.
- Advises and coach teams and staff to assure our actions and activities are in compliance with the requirements of external customers, laws, regulations and regulatory agencies.
- Collaborate with new product development teams to assure conformance with applicable regulatory requirement, i.e. FDA, UL, etc.
- Collaborate with customers, agencies, and other people outside of the company to achieve regulatory objectives.
- Represent the company as lead interface with regulatory agencies and authorities, i.e. FDA.
- Manage decision-making and problem-solving surrounding regulatory issues within teams as well as within regulatory affairs.
- Travel is required, including overnight and out of the country.

Qualifications:

Minimum Qualifications:

- Bachelor's degree (preferably in Engineering) or equivalent experience required. Master's degree preferred.
- Minimum of three (3) years of experience managing regulatory affairs at a manufacturer of Class II Exempt medical devices.
- Minimum of five (5) -ten (10) years of Regulatory Affairs experience.
- Regulatory Affairs Certification preferred.

Additional, Knowledge, Skills & Abilities:

- Excellent verbal and written communication skills.
- Experienced in managing regulatory submissions for US and International markets.
- Ability to liaise, negotiate and interact with FDA and international regulatory agencies.
- A thorough understanding of regulatory agencies submission processes.
- Strong interpersonal and team building skills.
- Excellent teamwork, leadership, organizational, and negotiating skills.
- Excellent working knowledge of Microsoft Office suite (Word, Excel, PPT).

Please submit resume to careers@rauland.com and reference RBRADRA or apply at: <https://home.eease.adp.com/recruit/?id=1091831>