The **Regulatory Affairs Manager** will be responsible for managing all facets of regulatory support to market CONMED products. This includes developing regulatory submissions, managing departmental projects, creating and reviewing labeling, providing guidance and consultation for domestic and international regulations, interacting with governmental agencies and managing a staff of regulatory professionals.

Duties & Responsibilities:

- Manage the development and implementation of regulatory strategies of RA staff for new and modified devices through interface with Global regulators, reviewing international authorities, and Global internal team members.
- Direct submissions and negotiations with FDA , Notified Bodies, and other agencies as needed including pre-submission identification of requirements and strategy and post-submission negotiations to ensure timely approval
- Maintain proficiency on regulatory requirements and develop and maintain rapport with Regulatory Agencies, group leaders and ancillary personnel.
- Keep Senior Management informed of regulatory status of products and significant regulatory issues
- Develop staff through daily interactions and coaching, provide guidance in technical and Regulatory matters and maintaining strong business relationships with Marketing, R&D, and other cross functional areas.
- Provide guidance on regulatory requirements for promotional and educational materials.
- Assist with departmental policy, procedure development and implementation.

Requirements:

- Minimum 7 years of experience with a bachelor's degree, 5 years of experience with a master's degree of direct relevant experience in Regulatory Affairs.
- Must include proof of hands on 510K submission experience.
- Must possess strong skills in the areas of organization, decision-making and communication.
- Previous leadership experience is highly preferred.

About CONMED

CONMED is a global medical technology company that specializes in the development and sale of surgical and patient monitoring products and services that allow our physician customers to deliver high quality care and as a result, enhanced clinical outcomes for their patients.

With products that are recognized as technological leaders by the specialties they serve, healthcare professionals within the Orthopedic, Laparoscopic, Robotic & Open Surgery, Gastroenterology & Pulmonology and Cardiology & Critical Care specialties have come to value the CONMED name across the world.

Please click here to apply: https://careers.conmed.com/job/CONMGLOBALR5433/Regulatory-Affairs-Manager