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Regulatory Affairs Engineer

Position Summary:

Develop, manage, and implement worldwide regulatory approval and compliance strategies for new and existing products. Manage regulatory projects and interface directly with FDA.

Specific Responsibilities:

- Operate the QMS including internal/external audits, improvements and employee training
- Compile successful, on-time regulatory submissions for 510(k) clearance and CE mark.
- Maintain productive, constructive relationships with FDA and notified-body reviewers.
- Review and edit labeling, clinical study protocols, and marketing material for regulatory compliance.
- Quickly solve regulatory problems for internal marketing, sales, and engineering customers.
- Guide product development teams in providing content for technical files and design history.
- Provide guidance for corporate business development efforts, particularly regarding the potential impact of future US and international regulations.
- Assist with departmental policy and procedure development and implementation.

Education:

Bachelor of Science degree in engineering or engineering technology preferred (Computer Science, Electrical Engineer).

Experience:

- Requires three years or more experience overseeing a registered quality system in an electronic design and manufacturing environment.
- Demonstrated working knowledge of ISO 13485 and FDA GMP.
- Product Development Lifecycle experience.

Skills/Job Knowledge/Ability:

- Ability to interpret engineering drawings and electrical schematics.
- Must be able to utilize standard mechanical and electrical instruments, functional gauges, and test rigs.
- Must be able to comprehend and implement regulatory standards with little assistance from others. and provide engineering with information necessary to design medical instruments and accessories that meet safety standards and regulations.
- Experience with ISO quality policies and audits.

Come play a leading role in the growth of Cadwell Laboratories, Inc., a world-renowned medical equipment leader. Join Cadwell and be a part of the team that makes ideas come to life!

Send your resume to:
cathya@cadwell.com