Senior Regulatory Affairs Specialist

Job Location- US-Remote

Overview:

Oversees/Manages the regulation process for products requiring regulatory agency licensing, registration or clearance, including filing necessary applications/submissions. Coordinates the accumulation of technical information and creates submissions for medical devices for approval, license, registration or clearance in any region.

Essential Functions:

- Responsible for performing CMC activities for assigned products for US, EU MDR/IVDR, Health Canada and rest of the world (ROW).
- Responsible for development of product launch strategy, including documenting testing requirements, submission pathways, and anticipated approval/clearance timelines for defined target markets.
- Responsible for the interactions with the FDA, the EU Notified Body, and Health Canada. Keep updated on all country requirements and changes.
- Participate in change control meetings. Review and approve requests. Notify Regulatory Bodies of changes that impact clearances, licenses, etc.
- Perform labeling reviews/approvals as required.
- Researching and consolidating regulatory requirements to enable future development of regulatory strategies for all regions.
- Create and maintain registrations procedures/protocols.
- Work closely with internal and external customers to achieve success.
- Additional duties and/or modifications to job description may occur at any time.
- Create 510(k) submissions for Domestic Market (FDA). Submit Q-Submission Meetings, such as pre-submission and issue meetings, to the FDA as needed.
- Create Technical Files, Design Dossiers and Health Canada notifications of product changes for submission to the designated Regulatory Agency to obtain/maintain CE Marking.
- Review and Maintain (MDD) Technical Files and Design Dossier/(MDR/IVDR) Technical Documentation after receiving CE Marking.
- Create New License Submissions, Amendments, and Fax Back applications for Health Canada.
- Respond to questions from regulatory agencies during review/submissions.
- Support and assist with the external audit program and participate in inspections and audits by Regulatory Bodies.
- Complete Regulatory Corrective and Preventive Actions generated from audit findings.
- Develop and maintain policies and procedures regarding to regulatory submissions and processes.
- Create and maintain, a foreign registration database of all current in country registrations and licenses.
- Partnering with International regulatory contacts to understand requirements for product registrations for new and modified products.
- Partnering with International regulatory contacts to plan, develop and submit product registration applications for new, modified products and/or registration renewals.
- Coordinate with applicable stakeholders, to support submissions and testing requirements.
- Attend and/or lead Regulatory meetings.

Requirements:

- Bachelor's degree (B. A./B.S.) from four-year college or university; or three to five years related experience and/or training; or equivalent combination of education and experience
- Certificates, Licenses, Registrations: RAC certification is preferred.
- Other Skills and Abilities: Knowledge and understanding of US, EU MDR/IVDR and international medical device regulations.
- Regulatory: 5 years (Required)
- PMA experience (ideally submissions involving software): 2-3 years
- FDA, EU: 4 years (Required)

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