Job Details

Regulatory Affairs Associate (MDSAP & Medical Device Registration)

SABA LASE TECHNOLOGIES INC. is seeking an experienced and highly skilled **Regulatory Affairs Associate** to join our team. The ideal candidate will be responsible for managing the regulatory affairs process for the registration of our medical devices (single-use fiber optic laser surgical probes and laser diodes for surgery) in Canada, ensuring compliance with Canadian medical device regulations, including MDSAP (Medical Device Single Audit Program) and Health Canada's Medical Device Regulations (MDR).

The **Regulatory Affairs Associate** will work closely with cross-functional teams including R&D, Quality Assurance, and Manufacturing to navigate regulatory pathways, maintain product registrations, and ensure that all regulatory documentation is complete and accurate for Health Canada submissions.

Key Responsibilities:

Regulatory Strategy & Submission:

- Prepare and submit product registration dossiers for medical devices to **Health Canada** in accordance with the Medical Device Regulations (MDR).
- Develop and execute regulatory strategies for the registration of single-use fiber optic laser surgical probes and laser diodes for surgery.
- Assist in the preparation of **Device License Applications (DLAs)** and **Medical Device Establishment License (MDEL)** applications.
- Ensure that products comply with **Canadian Medical Device Regulations (CMDR)** and related standards (e.g., ISO 13485, IEC 60601, ISO 14971).

MDSAP Compliance:

- Understand and support the implementation of MDSAP audits, which include regulatory requirements for Canada, the US, Japan, Brazil, and Australia.
- Prepare the company for **MDSAP audits** by working closely with internal teams to ensure readiness and compliance.
- Maintain and update MDSAP compliance documentation and respond to any findings during audits.
- Coordinate with external audit organizations to ensure successful completion of MDSAP audits.

Product Lifecycle Management:

- Provide regulatory guidance during the development of new products, ensuring all regulatory requirements are integrated from the concept phase through to post-market.
- Assist in managing the lifecycle of products, including post-market surveillance, vigilance reporting, and renewal of licenses.

Regulatory Intelligence:

- Stay current on changes to Health Canada regulations, MDSAP updates, and global regulatory trends impacting medical devices.
- Monitor relevant legislative changes and ensure that SABA LASE TECHNOLOGIES stays compliant with all regulatory requirements.
- Advise the company on regulatory implications of product changes, innovations, and new technology.

Cross-Functional Collaboration:

- Work closely with Quality Assurance, R&D, and Manufacturing to ensure that regulatory requirements are met at every stage of product development, from design to market launch.
- Support product recalls or corrective actions as necessary, ensuring regulatory reporting is completed on time.
- Provide regulatory guidance to other teams for product labelling, clinical trials, and marketing materials to ensure compliance with Canadian regulations.

Documentation & Reporting:

- Maintain up-to-date regulatory documentation, including submission files, audit records, and product-related certificates.
- Prepare regulatory reports and summaries for management, ensuring clear communication on regulatory status, potential risks, and compliance progress.

Qualifications & Requirements:

Education:

- Bachelor's degree in Life Sciences, Engineering, Regulatory Affairs, or a related field. A Master's degree or professional certification (e.g., RAC- Regulatory Affairs Certification) is a plus.

Experience:

- Minimum of **3-5 years of experience** in regulatory affairs, specifically in the medical device industry.
- Proven experience in **Health Canada medical device registration** and understanding of the **Canadian Medical Device Regulations (CMDR)**.
- Strong understanding and hands-on experience with **MDSAP** (Medical Device Single Audit Program), including audit preparation and compliance management.
- Familiarity with the regulatory requirements for **laser-based medical devices** or similar technologies (e.g., fiber optics, diodes, surgical equipment) is highly preferred.

Knowledge:

- In-depth knowledge of **Health Canada** regulations (MDR, CMDR, MDEL), and standards such as ISO 13485, ISO 14971, IEC 60601, and ISO 10993.
- Thorough understanding of the **MDSAP** process and requirements for audits.
- Knowledge of **FDA**, **CE Marking**, and international medical device regulations is an asset.

Skills:

- Strong analytical and problem-solving skills, with the ability to evaluate complex regulatory requirements and identify solutions.
- Excellent organizational skills and attention to detail in managing regulatory submissions and documentation.
- Strong written and verbal communication skills, including the ability to communicate complex regulatory information to both technical and non-technical stakeholders.
- Ability to manage multiple tasks and meet deadlines in a fast-paced, dynamic environment.

Other Requirements:

- Ability to work independently and as part of a cross-functional team.
- A proactive approach to regulatory affairs, with a demonstrated ability to anticipate challenges and address them in a timely manner.
- Experience working with regulatory software and databases for managing submissions, licenses, and audits is a plus.

Desired Attributes:

- **Team-Oriented:** Ability to collaborate effectively with internal teams, external vendors, and regulatory bodies.
- **Detail-Oriented:** High level of accuracy and attention to regulatory compliance details.
- **Proactive and Solution-Focused:** Demonstrates initiative to stay ahead of regulatory changes and resolve issues before they impact product timelines.
- **Regulatory Expert:** Deep understanding of the regulatory landscape for medical devices, especially in the context of laser and fiber-optic technologies.

Why Joining us?

- **Innovative Products:** Work on cutting-edge technologies in the medical device industry, specifically in the rapidly advancing field of laser-based surgical tools.
- **Impact:** Be part of a company that is committed to improving patient care and surgical outcomes with high-quality, precision medical devices.
- **Collaborative Environment:** Join a dynamic, collaborative team dedicated to regulatory excellence and product quality.
- **Career Growth:** Opportunities for professional development, certification, and growth within the regulatory affairs field.

How to Apply:

Please send your resume and cover letter to Info@sabaphotonics.com. In your cover letter, please highlight your experience with MDSAP, Health Canada medical device registration, and your familiarity with the regulatory processes specific to laser-based medical devices.

SABA LASE TECHNOLOGIES INC.
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