JOB DESCRIPTION

I. POSITION SUMMARY:

The Senior Regulatory Affairs Specialist is responsible for researching scientific and regulatory information for review and preparation of regulatory submissions intended for the FDA and EU and other regulatory authorities. This position will work to ensure approval of products. In addition, this person is responsible for review of promotional material and labeling for compliance with FDA and EU regulations and overseeing annual establishment registrations and listings. This position works under minimal supervision and reports to the Director of Regulatory Affairs.

DUTIES AND RESPONSIBILITIES:

- Contribute to the development and implementation of new product regulatory strategies for assigned products in the U.S., enabling products to get to market as quickly as possible;
- Author and review regulatory documentation, checking for accuracy, scientific consistency, compliance to regulations and completeness;
- Clearly communicate recommendations to cross-functional teams;
- Participate in cross-functional teams and lead and/or participate in regulatory project teams working on developing product claims for labeling and promotion as well as commercialization of new products;
- Translate regulatory strategy into clear and measurable objectives and ensure that the appropriate processes are followed;
- Act as company liaison to the regulatory authorities for assigned products with moderate supervision. Communicate results of these interactions with the company;
- Develop strategies to address regulatory authority requests and requirements and lead execution of strategy;
- Prepare and coordinate accurate and timely submissions to the FDA and EMA or other regulatory authorities, as needed;
- Ensure regulatory compliance of marketed products;
- Review and approve promotional materials and labeling changes, maintain U.S. dossiers (Investigational New Drug [IND], New Drug Application [NDA] and DMFs) including Annual Reports and Periodic Safety Reports;
- Proactively identify regulatory issues/risks and design/execute mitigation plans;
- Maintain current knowledge of regulations and industry environment and provide guidance on potential and evolving trends. May act as a company liaison to industry trade associations;
- Create and manage strong network with key stakeholders such as marketing, legal, and other scientific personnel that facilitate collaboration;
- Capable of performing tasks with minimal supervision.
- Perform other duties as assigned.

SKILLS AND ABILITIES:

- Excellent skills in written and verbal communication.
- Substantial experience with multitasking in a deadline controlled and highly regulated environment.
- Goal-oriented, proactive, able to multi-task, strong organizational skills.

- Literacy with electronic document management systems and experience with electronic submission.
- Ability to work through scheduling demands and conflicts with composure and diplomacy.
- Balance strategic thinking and strong analytical skills with ability to execute. Detail oriented with strong written, verbal communication and presentation
- Interpersonal, communication and negotiating skills.

MINIMUM REQUIREMENTS:

- Bachelor's degree is required.
- An advanced degree in the life sciences (Ph.D., M.D., or M.S.) or equivalent combination of education and experience is preferred;
- Experience to include Ph.D., M.D., or PharmD. with a minimum of two (2) years of Regulatory experience, OR M.S. with a minimum of six (6) years of Regulatory experience, OR a Bachelor's degree with at least 10 (10) years of regulatory, or other relevant experience
- Knowledge and experience of U.S. FDA and EU regulations and standards.
- Recent experience in regulatory submission and approval activities with INDs/NDAs/DMFs.
- Excellent computer skills, particularly with Microsoft Office products.

II. COMPLEXITY OF WORK:

Requires excellent verbal and written communication skills, tact, accuracy, and the ability to prioritize work and work well under extreme pressure. Ability to work independently, interface with various levels of administration and management. Must maintain all levels of confidentiality and have a professional, positive attitude towards the job.

III. SUPERVISION OF OTHERS:

Yes.

IV. PERSONAL CONTACTS REQUIRED:

Personal contacts made routinely as part of the job include various administrative and managerial staff, consultants, customer, and vendors.

V. RESPONSIBILITY FOR ACCURACY AND SERIOUSNESS OF ERROR:

Errors have the potential to be extremely costly. Problems can arise if duties are not fully or properly performed. Financial loss to Emmaus Medical can result from errors.

VI. HANDLING CORRESPONDENCE:

Incoming correspondence is not limited to distributing and responding to various items related to a specific study or product or other Emmaus Medical business information. Outgoing correspondence includes but is not limited to meeting materials, letters, marketing materials, and memoranda.

VII. RESPONSIBILITY FOR CONFIDENTIAL INFORMATION:

The majority of information processed by the Senior Regulatory Affairs Specialist is extremely confidential and requires utmost discretion in handling. In addition, the Senior Regulatory Affairs Specialist is often referred unusual and sensitive requests for information, which may involve other office staff. The Senior Regulatory Affairs Specialist is required to keep this information confidential and not discuss it with the other staff members in the office.

VIII. UNUSUAL JOB REQUIREMENTS:

May be required to perform other duties as appropriate to the needs of Emmaus Medical that are not listed and in addition to this job description.