JOB DESCRIPTION

I. POSITION SUMMARY:

The Regulatory Affairs Specialist's primary function is to support the regulatory activities for pre and post-marketed products. The Regulatory Affairs Specialist will participate in activities to ensure compliance with worldwide regulatory requirements and must work well under deadlines and have excellent attention to detail.

DUTIES AND RESPONSIBILITIES:

- Prepare and review submissions (i.e., NDA, MAA, etc.) to obtain various worldwide approvals to commercially distribute products.
- Support the preparation and review of materials (i.e., INDs, Protocols, Investigator Brochure) for conducting clinical investigations in the U.S., EU countries and other countries.
- Prepare and review required submissions (progress reports, annual reports, etc.) to facilitate the continuation of clinical studies.
- Participate in the review and submission activities (annual reports, periodic safety update reports, etc.) to support the maintenance of marketed products.
- Support product registrations for international markets as required.
- Participate in project development teams and review plans, reports, risk management and design reviews associated with product and process projects.
- Perform other duties as assigned.

SKILLS AND ABILITIES:

- Excellent written and verbal communication.
- 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.
- Interpersonal, communication and negotiating skills.

MINIMUM REQUIREMENTS:

- Bachelor's degree required, preferably in a scientific discipline. An advanced degree is preferred.
- 3 to 5 years of biopharmaceutical experience, of which at least 4 years including direct hands-on regulatory affairs experience and successful IND and NDA/MAA submission 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.
- Balance strategic thinking and strong analytical skills with ability to execute. Detail oriented with strong written, verbal communication and presentation
- 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:

No.

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 Regulatory Affairs Specialist is extremely confidential and requires utmost discretion in handling. In addition, the Regulatory Affairs Specialist is often referred unusual and sensitive requests for information, which may involve other office staff. The 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.