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JOB DESCRIPTION

Position Title: Regulatory Affairs Specialist

Reports to: Director, Regulatory Affairs

Department: Regulatory Affairs

FLSA Status: Exempt

PURPOSE OF JOB:
Main areas of responsibility are to provide direct support to the regulatory department and to maintain auditable regulatory files and correspondence ensuring compliance with FDA and international regulations and guidelines. Responsible for coordinating efforts associated with the preparation of regulatory documents or submissions including establishing and tracking regulatory project timelines, status and documents.

MAJOR DUTIES AND RESPONSIBILITIES:
- Responsible for assisting with the coordination and preparation of regulatory submissions (510(k), IDE, PMA, IND, NDA and international submissions) to ensure compliance with FDA and international regulations and guidelines.
- Meet the general day-to-day administrative needs of the regulatory department such as filing and maintaining submission logs and regulatory correspondence including compiling and maintaining regulatory documentation databases or systems.
- Responsible for coordinating the preparation of regulatory documents or submissions including document formatting, printing, binding, tracking regulatory project timelines, status and documents.
- Responsible for generating electronic copies of the submissions in compliance with FDA and other regulatory guidances,
- Perform regulatory research and identify and interpret regulatory rules or revisions, guidance documents and standards and ensure that they are communicated through corporate policies and procedures.
- Provide technical/QC review of data and/or reports that will be incorporated into regulatory submissions to assure scientific rigor, accuracy and clarity of presentation.
- Write or update standard operating procedures, work instruction or policies.
- Partner with all disciplines within organization to obtain and/or provide information for regulatory submissions.
- Provide regulatory support for quality assurance, compliance and clinical affairs activities.
- Review product labeling, batch records, specification sheets or test methods for compliance with applicable regulations and policies.
- Assist with product complaint handling and determine reportability.
- Conduct regulatory assessments, review and approve manufacturing and design changes as appropriate.
- Review and approve promotional materials to ensure consistency with regulatory approvals.
- Coordinate meetings as directed.
- Support company goals and objectives, and ensure compliance with policies and procedures, FDA and International regulations.

EDUCATION REQUIREMENTS: Minimum of BS in Life Sciences or other technical discipline.

EXPERIENCE REQUIREMENTS:
- Minimum of 2 years' regulatory affairs industry experience with Class II and III medical devices or IND/NDA drug submissions.
- Experience with drug/device combination products is highly preferred.

OTHER QUALIFICATIONS:
- Must possess excellent written and verbal communication skills.
- Must be detail oriented with well-developed organizational and analytical skills.
- Highly proficient in Microsoft Word, Excel, Power Point and Adobe Acrobat.
- Must have outstanding interpersonal skills, work effectively on teams, and maintain composure in stressful situations and under tight deadlines.