JOB DESCRIPTION

Position Title: Regulatory Affairs Manager

Reports to: Director Regulatory Affairs

Department: Regulatory Affairs

FLSA Status: Exempt

PURPOSE OF JOB: Plan and implement global regulatory strategies for drug/device combination products from development through marketing approval. Responsible for providing regulatory leadership in the support of IND/NDA and international regulatory applications and ensuring compliance to all applicable regulations and standards.

MAJOR DUTIES AND RESPONSIBILITIES:

- Regulatory representation and leadership to cross-functional product development teams, development of regulatory strategies and support for Intersect ENTs clinical and non-clinical development programs, marketing applications and post-marketing activities.
- Responsible for project timelines and management of IND/NDA and global regulatory submissions.
- Lead regulatory activities including planning and reviewing of chemistry, manufacturing and control and nonclinical sections of regulatory submissions.
- Coordinate and prepare regulatory submissions (IND, NDA, IDE, 510(k), PMA) to ensure compliance with FDA and international regulations and guidelines.
- Support IND application including responsibility for safety reporting requirements, supplements and annual reports.
- Provide global CMC regulatory guidance, especially as it pertains to current thinking related to combination drug/device products.
- Responsible for developing and maintaining department SOPs with an emphasis on drug regulations.
- Perform research regarding regulatory strategic recommendations, and new and revised governmental regulations.
- Accountable for successful negotiations and interactions with domestic and foreign regulatory agencies on assigned projects.
- Participate with all disciplines within the organization to obtain and/or provide information for regulatory filings.
- Provide proactive regulatory intelligence in areas of a competitive nature and also keep abreast of changes in agency regulations and requirements (e.g. FDA, EMEA).
- Maintain well-organized, auditable regulatory files.
- Provide regulatory support for quality assurance and regulatory compliance activities.
- Provide regulatory guidance regarding analytical methods and requirements pertaining to combination products.
- Provide regulatory assessments for anticipated analytical, manufacturing and packaging changes.
- Represent RA functional area in the review and approval of Engineering Change Orders (ECO).
- Provide regulatory guidance with regard to preparation, review and approval of labeling and promotional materials.

EDUCATION REQUIREMENTS: Minimum of BS in life sciences, engineering, or equivalent required.

EXPERIENCE REQUIREMENTS:

This job description is not all inclusive. Incumbents may be required to complete other miscellaneous responsibilities as required.

- Minimum 6 years' experience in regulatory affairs medical device/biopharmaceutical industry with submission project management experience.
- Experience in developing and submitting successful IND/NDA submissions with a thorough understanding of the drug development process, FDA regulations and ICH guidelines.
- Excellent verbal and written communication skills.

OTHER QUALIFICATIONS:

- Experience with submitting documents in CTD and eCTD format.
- Must be detail oriented with well-developed organizational and analytical skills.
- Highly proficient in Microsoft Word, Excel, Power Point and Adobe Acrobat.
- Must enjoy working in a fast-paced startup environment with proven ability to be flexible and adaptable within a changing dynamic environment.

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