



REGULATORY AFFAIRS SPECIALIST

Employment Type: Full-Time / Exempt
Department: Clinical & Regulatory / 410
Effective: October, 2021

Position Summary:

Responsible for the hands on regulatory activities required to submit, approve and launch new products and for the maintenance of existing commercialized products. Executes regulatory activities according to project plans to assure new products meet submission, approval and commercial launch goals. Related activities include compiling and writing FDA and IVDR reports as well as coordinating the completion of technical file requirements across multiple departments.

Required Education, Experience and Skills:

B.S. or B.A. degree in an applicable scientific or health science field such as biochemistry, chemistry, pharmacy or pharmacology required. Some hands-on experience in Regulatory Affairs, or a combination of an advanced degree in Regulatory Affairs or related field and relevant practical training in the field, is required. Minimum of two (2) years in medical device or other medical products/healthcare/selfcare industry. Excelled analytical skills and the ability to apply policies and general regulations to specific products or projects. Good verbal and written communication skills. Ability to work effectively on project teams. Knowledge and understanding of scientific, regulatory and trade dress terminology.

Essential Functions/Major Responsibilities:

- Responsible for compliance with the company's quality system requirements through training and adherence to policies, procedures and processes.
- Generate regulatory plans and reports compliant with ISO, ICH, and IVDR requirements.
- Update/amend relevant SOPs to maintain ongoing regulatory compliance.
- Facilitate the document control of pertinent regulatory documents through the Quality Management System.
- Work with multiple departments to ensure regulatory goals and timelines are met.
- Perform other assignments or projects as directed.

NOTE: This Job Description is intended to outline general functions of relevant position and shall not be considered as comprehensive definition of specific tasks that will be required. Furthermore, specific duties of this position are subject to change as Company, Department and circumstances change. All employees are expected to perform their duties within their ability as required by the job and/or as requested by management.