

Regulatory Submissions Specialist

Responsibilities:

The candidate will be responsible for coordinating and preparing international and domestic regulatory submissions, annual registrations, safety reports, as well as other regulatory activities in paper and/or electronic format in accordance with current requirements and electronic submission specifications. Maintains regulatory product indices and submission records in paper and/or electronic format. The candidate will ensure the elements; quality, accuracy and format of regulatory submissions comply with applicable laws, regulations and corporate standards. The successful candidate must be self-motivated, detail oriented, accurate, organized, be able to multi-task, and capable of working collaboratively with colleagues in other departments.

Requirements:

- A bachelor's degree in a scientific discipline, with a minimum of 2-3 years of regulatory affairs and/or documentation management experience.
- Coordination and preparation of regulatory filings and other documents as needed.
- Control electronic templates for IND annual reports, SAE Reporting, IND Amendments, and other document types as needed.
- Publish submission applications using a variety of tools such as authoring templates and electronic publishing tools or paper submission compiling software.
- Maintain and archive Regulatory files both electronic and paper.
- Provides expertise to project teams regarding electronic (eCTD) submissions and submission technical issues.
- Advanced computer skills-word processing, spreadsheet and database programs.
- Capable of handling multiple projects simultaneously.