Regulatory Affairs Associate

Responsibilities

The qualified candidate is responsible for drafting, editing and compiling IND, investigator's brochures, overall summaries, annual reports, correspondence and other regulatory documents to the US FDA to ensure compliance with applicable regulations and guidance.

The candidate must be able to prepare, review, edit and develop documents in ICH, CTD and CFR formats and be knowledgeable of electronic submission formatting (eCTD).

Support regulatory file maintenance to ensure prompt and accurate access to company regulatory information regarding approvals and renewals.

Collaborate with cross functional teams/contractors to obtain relevant information and subsequent review of submission content as needed.

Provide initial correspondence and responses to regulatory agencies regarding product information and other issues.

The candidate may be involved in the development, preparation and writing of other client documents and presentations.

Monitor emerging regulatory changes and determine and initiate changes to organizational processes, products in the field and promotional material to ensure compliance.

Qualifications

Qualified candidates must have minimum bachelor's degree in Biology, Chemistry, Medical Science, Pharmaceutical Science, or related scientific discipline with at least 2-5 years of relevant regulatory experience and/or quality assurance experience, preferably in the pharmaceutical industry is strongly preferred. Ph.D. degree is preferred.

The candidate must possess excellent oral and written communication skills.

Chinese language skill is strongly preferred.