AKRONBIOTECH

Regulatory Affairs Specialist

GENERAL DESCRIPTION:

- Provide strategic guidance to clients to ensure that developmental activities, manufacturing, and analytical controls comply with relevant regulations, guidelines, and industry standards.
- Compile, organize and manage the production of clear and persuasive CMC-related regulatory submissions for pharmaceuticals, biologics, and combination products.
- Prepare and review electronic submission such as eCTD and others.
- Oversee outsourced CMC activities, such as process and analytical method development activities, manufacturing, analytical testing, formulation development, and stability testing.
- Draft and review master batch records and protocols and reports relating to analytical method development and validation, process development and validation, stability testing, investigations, etc.
- Develop and manage CMC-related project timelines.
- Prepare pre-clinical regulatory documents when needed.
- Supervise and guide cross functional project team professionals and support personnel.
- Ensure that regulatory submission timelines for assigned projects are met.
- Ensure that appropriate CMC documentation is archived in designated systems.
- Participate in project development teams and review plans, reports, risk management and design reviews associated with product and process projects.
- Perform other duties as assigned.

WORK EXPERIENCE REQUIREMENTS:

- Experience in eCTD publishing (Required).
- 1 year industrial manufacturing regulatory experience (Required).
- 1-3 years experience in product registration in EU, TGA, FDA (Preferred).
- Experience within a pharmaceutical/medical device organization and current Good Manufacturing Practices (cGMPs)/Quality System (QS) Regulation is strongly preferred.
- Proficient in computer skills with eCTD software, template creation for submission, Word/Excel/MS Office Suite and ERP systems.

EDUCATION REQUIREMENTS:

- Bachelor’s Degree in science, biotechnology, or related discipline.