AKRONBIOTECH

Regulatory Affairs Associate

GENERAL DESCRIPTION:

- Prepare, compile and develop product registration data for the semi-regulated and regulated market.
- Be well informed about eCTD, ACTD & country specific guidelines.
- File regulatory documents within budget and timeline.
- Interact with various departments/teams to collect documents required for dossier compilation on time as per regulatory norms.
- Coordinate with manufacturing facilities for product samples, specifications, laboratory reports and packaging materials.
- Interact with various external regulatory agencies.
- Review the quality and analytical data as per the pharmacopoeia, specification, batch manufacturing records, stability, finished product / packaging material data for the purpose of compilation of the dossier.
- Review and manage applications for License and DMF.
- Review and respond to technical queries related to product registration from FDA.
- Maintain an online report of various submission status as well as queries at various stages of all countries.

WORK EXPERIENCE REQUIREMENTS:

- Experience in eCTD publishing (Required).
- 1 year pharmaceutical regulatory experience (Required).
- 1 year pharmaceutical product registration experience in non-US country (Required).
- 3-6 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.