Job Description

Regulatory Affairs Specialist/Manager

Description:

I-Mab biopharma is a growing company headquartered in Shanghai aiming to be a China-based global player in innovative biologics. I-Mab's US Office, located in Gaithersburg MD, is an integral part of I-Mab R&D to leverage the resources and development strategies to support I-Mab's Global Portfolio. The Regulatory Affairs Specialist/Manager, supervised by Associate Director of Regulatory Affairs, is responsible to prepare and submit regulatory documents to health agencies.

Location: Gaithersburg, Maryland (Full time on site)

Responsibilities

• Draft and manage a variety of regulatory documents and submissions in eCTD via ESG to FDA, which include but not limited to, Investigational New Drug applications (INDs), Annual Reports/DSUR to INDs, Investigator's Brochures (IBs), information amendments (nonclinical, clinical, and CMC), and any other regulatory dossiers;

• Review regulatory documents for their compliance with pertinent guidance and technical preparedness, including nonclinical CMC reports, general investigational plan, and IB, etc;

• Assist to manage timelines for the drafting, review, revision, and submission of regulatory dossiers;

• Track on-going regulatory activities and plan for up-coming ones with the key contributors from cross-functional team to ensure timely delivery of regulatory items;

• Support the development of the Standard Operating Procedures (SOPs) of Regulatory Affairs;

• Support due diligence on regulatory intelligences, landscapes, and strategies as assigned.

Qualifications:

• Minimum two-year working experiences in regulatory submission is a must.

• Hands-on experiences on eCTD publishing tools and software, xml file editing.

• Strong skills in MS Word, Excel, Outlook, SharePoint, and Adobe Acrobat DC is highly desired.

• Minimum BS degree in life science (e.g. Biology, Chemistry, Pharmacy or related fields).