



About BioNet

BioNet is a biotech company focusing on bio-innovation and access to genetically-designed vaccines.

BioNet is the world's only manufacturer of licensed recombinant pertussis vaccines containing a genetically-inactivated pertussis toxin (PTgen).

BioNet's main locations are Bangkok, Thailand and Lyon, France with a vaccine manufacturing plant in Ayutthaya, Thailand. Our team of more than 200 people across the globe are fully dedicated to the development, manufacturing and supply of vaccines against re-emerging and pandemic diseases.

Due to our business expansion, we are looking for competent, enthusiastic and highly qualified individuals to join our team.

Regulatory Affairs Pharmacist

Job Location

Ayutthaya Office (Hi-Tech Industrial Estate)

Job Summary

Regulatory Affairs Pharmacist will be supporting the Regulatory Affairs Department in assisting the regulatory activities for the vaccine projects at Ayutthaya Site, submitting for permits and filing the dossiers/dossier variations according to requirements of Thai FDA, WHO, and relevant regulatory authorities, and coordinating between regulatory authorities and BioNet functional teams for vaccine product development and registration.

Key Responsibilities

- Provide and keep track of regulatory requirements of relevant activities on vaccine development process and licensing.
- Prepare and manage dossier of pre-marketing and post-marketing filing and submission until obtaining market authorization of a product.
- Maintain regulatory compliance.
- Update stakeholders of relevant changes in regulations and prepare action plans to comply with the regulations.

Job Qualifications

- Minimum of 2-3 years of experience in Regulatory Affairs and pharmaceutical industry.
- Bachelors' Degree in a Pharmacy.
- Fully fluent spoken and written English.
- A keen interest in vaccinology.
- Demonstrates knowledge of Thai FDA, eCTD and international regulatory requirements and process, content and guidelines according to GMP, GDP, GLP, and GCP.
- Ability to multitask and deliver on multiple projects.
- Ability to work well independently as well as part of a team.
- Good communication and problem solving skills.