BioNet

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.

Quality Assurance (Operational Quality & Batch Release Section)

Job Location
Ayutthaya Office (Hi-Tech Industrial Estate)

Job Summary
Monitors product quality to ensure strict compliance with Pharmaceutical Good Manufacturing Practices according to Thai Law (equivalent to PIC/s GMP) and other relevant GxPs as well as Marketing authorization.

Key Responsibilities
- Quality management in strict compliance with relevant GxPs.
- Product Quality and Marketing authorization compliance.
- Operational quality at the shop floor level to ensure strict compliance to the GMP, Quality Management System and local SOPs.
- Safety & Biosafety – manage the work place to prevent any accident in Operational Quality and Batch Release section.
- Customer service (Respect of company's project/ production and testing schedule).

Activity
The followings are required, but not limited to, activities of this person:
- Coordinate with team members to ensure the assigned works are performed in a timely manner in order to meet project timelines.
- Defines operational quality system to promote and provide quality support at the shop floor level and assess it according to GMP and risk analysis.
- Ensures robustness and efficiency of the Quality management system implementation in relevant departments, i.e. personnel training, self-inspection, management review, external audit, supplier quality assurance, quality technical agreement, product recall and complaint etc.
- Implements and integrates quality risk management in the quality management.
- Ensure that impact of change control has been properly evaluated before implementing.
- Ensure that deviations in quality system are properly reported, investigated and corrective/preventive actions are implemented in a timely manner.
- Review and update standard operating procedures, specifications, protocols and records relevant to the Quality management systems as assignment from Head of Quality Assurance.
- Report to Head of Quality Assurance of any incompliance events and/or discrepancies which could impact quality, safety of products or process.
- Develops the batch release process to ensure accurate batch decision.

109-GD-12-2024

Other assignments:
- Other jobs assigned by superiors to support the organization achievement as well as corporation in company rule and regulations, safety policy and all activities according to company policy.
- Work in compliance with the company's Health, safety & environment policy and procedures, regulations, requirement and manual.
- Report any incident, accident, near miss and any violations of the HSE or safe work practices including malfunctioning of the equipment or workplace hazards that he/she is aware of to the direct supervisor.
- Follow the health and safety including biosafety procedures related to the job functions, which includes the use of Personal Protective Equipment (PPE), safe operation of equipment, machinery, tools and handling of hazardous substances.

Job Qualifications
- Pharmacist
- 0-2 years of experience in Pharmaceutical or Biological Industry in GMP environment is beneficial.
- Fluent in both written and spoken English.
- Good knowledge of GMP and other relevant GxPs