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.

Senior Quality Assurance Officer-Operation Quality and Batch Release

Job Location
Ayutthaya Office (Hi-Tech Industrial Estate)

Job Summary
Operates Quality Management Systems to ensure strict compliance with Pharmaceutical Good Manufacturing Practices and other relevant GxPs as well as marketing authorization. Maintain andimprove the relevant system in Quality Assurance department.

Key Responsibilities
- Compliance with GMP, other relevant GXPs, Quality directives and SOPs and relevant regulatory and guideline.
- Assistance in implementation of Quality Management Systems.
- Maintain and follow up SOPs related with Quality Management Systems i.e. CAPAs,Deviation and Change control request and self-inspection etc.
- Operational quality at the shop floor level to ensure strict compliance to the GMP, Quality Management System, Quality Directives and local SOPs.
- Provide support in preparation of and during regulatory inspections.
- Customer services.

Activity-The followings are required, but not limited to, activities of this person:
Quality management system:
- Develop and keep up-to-date of SOPs relevant to the work.
- Implement, follow up and report of quality management tool i.e. Deviation, CAPA, change request, self inspection, external quality audit, out of specification complaint and recall etc.
- Coordinate for the self inspection and the auditing by external organization. Ensure self-inspection are executed in appropriate area base on risk assessment.
- Involve investigating all deviation and failure, reviewing investigation results and approving CAPA, Deviation closure and ensuring that corrective/preventive actions are implemented in a timely manner.

Operational quality:
- Ensure robustness and efficiency of the quality management system implementation at the shop floor level.
- Implement and integrate quality risk management in the quality management and operations.
- Provide operational quality support at the shop floor level and assess it according to GMP and risk analysis.
- Support the batch release process to ensure accurate batch decision.
- Notify any deviation or issues related to the batch release plan and/or results to superior.
- Conduct spot check in Production/QC Laboratories to verify strict application of SOPs, GMP and Quality directives.
- Reviews OOS report, deviation report, CAPA report as assignment from Head of Quality Assurance.

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- Ensure that deviations and OOS of product testing are properly reported, investigated and corrective/preventive actions are implemented in a timely manner.
- Report any non-compliance events and/or discrepancies, which could impact quality and safety of products or GMP to QA Supervisor. Other assignment.
- Other jobs assigned by superiors to support the organization achievement as well as corporation in company rule and regulations, safety & environmental policy and all activities according to company policy.
- Work in compliance with the company's Health, safety, biosafety & environment policy, procedures, regulations, requirement, manual and ISO14001 system.

Job Qualifications / Specifications

- Bachelor's degree or master's degree in Biology, Biochemistry, Biotechnology, Microbiology, Medical Technology or related fields.
- Good knowledge of GMP or GXPs practices/Biosafety.
- More than 2 years of experience in Pharmaceutical or Biological Industry or Research company or have the knowledge in QA or QC in GMP environment.
- Ability to correctly analyze, interpret and apply technical data towards practical actions and outcomes.
- Strong ability to achieve problem resolution using scientific rational with minimal supervision.
- Ability to learn new methods and techniques, perform multiple tasks simultaneously, keep accurate records, follow instructions, and comply with company policies.
- Fluent in both written and spoken English.
- Team working oriented with service minded and proactive working behavior.
- Be able to work on Microsoft office program and general office instruments.