Recruitment Information

1. PQ Project Management

Number of recruits: 2

Responsibilities

- Based on the company's project, assistthe project leader to comprehensively improve the quality management level and production capacity of the company, and promote the quality management level of the company to meet international standards;
- Through project operation, assist the project leader to improve the quality management concept of each team and improve the interpretation ability of domestic and foreign laws and regulations of each team;
- Supervise and promote various work in the project process, coordinate internal and external resources, support various departments to complete various works, and assistto solve key problems in the project process;
- Monitorthe work results regularly to ensure that the completion of the work reaches the expected level;
- Follow up the internal and external expert's review to ensure the implementation of project objectives.

Qualifications

- Master degree or above;
- Familiar with GMP system and WHO regulations, experience in production quality management is preferred, experience in WHO-PQ project is preferred;
- Capable of English listening, speaking, reading and writing;
- Good drafting and language expression skills;
- Strong ability of organization and coordination, able to carry out works according to the actual situation of the company.

2.InternationalLogistics

Number of recruits:1

Responsibilities

- Familiar with operation processforboth domestic and international logistics, customs clearance and inventory management process;

- Aware of the transport price in market, supervise the implementation ofresponsibilities for logistics system, control the costs for transportation and storage, constantly seek logistics suppliers, create reasonable competitive mechanism to reduce costs;
- Deal with emergencies in the process of product delivery, and report to relevant department leaders in time, regularly summarize and report various logistics management statements, responsible for the accuracy of data;
- Formulate and implement logistics work plan, summarize and improve logistics work standard, improve satisfaction of customers.

Qualifications

- Bachelor degree, major in international trade, logistics, management or related fields;
- Proficient in Office software such as Excel and Word;
- Work languages:English and Chinese;
- Good learning ability and communication skills.

3. International Registration of Vaccines

Number of recruits:1

Responsibilities

- Participate in international registration business, including preparation of international registration materials, communications, etc.;
- Track registration requirements of foreign regulatory systems;
- Communicate with departmentsrelated to production quality on technical issues;
- Translate relevant technical materials;
- Responsible for the arrangement and coordination of on-site inspection by foreign drug administration departments;

Qualifications

- Bachelor degree or above in Biotechnology, Pharmacy, Pharmaceutical English, Chemistry, Pharmaceutical Engineering, Biological Engineering or related fields;
- Work languages: English and Chinese.

4. Clinical Research Associate

Number of recruits:1

Responsibilities

Clinical Research

- Responsible for assisting Beijing Clinical Research Institute to draft clinical research protocols;
- Responsible for communicating with researchers to complete clinical trial summary report/phased progress report together;
- Improve / maintain electronic version of clinical trial information;
- Participate in the formulation of phase Ⅰ-Ⅲ clinical research plan for new drugs according to national regulations and R&D progress;
- Write / update the researcher's manual;
- Participate in the formulation of post-marketingphaseIV clinical trial plan according to production approval requirements and market demand.Select suitable research sites and researchers and organize the implementation;
- Participate in CDE technical review meeting, prepare technical materials and participated indefenses;
- Responsible for phase IVclinical research projects, participate in the development of project budget, control project implementation progress, timely communicate with internal and external aspects of project implementation.

Medical Support

- Provide medical support to marketing, participate in bidding and review/writing of publicity materials, etc.
- Participate in post-marketing pharmacovigilance and provide medical evaluation/management advice for adverse reactions as required
- Carry out the monitoring of papers /technical documents, timely track the latest development in product-related fields, update papers / database of technical document, etc.

On-site Management

- Responsible for draft and review of clinical trial monitoring plan, records and reports;
- Responsible for the coordination and management of the research site. Regularly report the progress of the test site to the project leader, PI, etc.
- Responsible for assisting researchers in the preparation and site-inspection for the one-time clinical trial institutions of vaccines;

- Preparation, handover and inspection of experimental vaccines and materials;
- Responsible for checking the implementation of regulations and ethics (e.g. informed consent, AE, protocol deviation, etc.);
- Verify the qualifications of researchers and the effectiveness of facilities and equipment;
- Verify the collection, storage and transportation of samples during the test;
- Responsible for the verification of the original test records to ensure that the data is complete, accurate and logical;
- Participate in the formulation of work plan/audit manual of clinical research site;
- Assist the researchers in completing the national inspections on clinical trials;
- Participate in site closing and document filing;
- Participate in the selection, evaluation and management of clinical trial partners;
- Participate in the training of researchers and CRAs;
- Assist to complete thediary cards, as well as the preparation and application ofInformed Consent Form, original records and other documents.

Qualifications

- Enterprise culture identification: identify with the company's development strategy and values, with a strong sense of responsibility and spirit of responsibility as well;
- Industry knowledge: familiar with the clinical research and development status of domestic and foreign biopharmaceutical (mainly vaccine) industry, able to timely track the development trends of the industry; familiar with relevant industry policies and regulations;
- Professional knowledge: major in clinical medicine / preventive medicine / pharmacy, etc.;
- Familiar with GCP and relevant guidelines for vaccine clinical research;
- Capable of organizing, implementing and quality management for supervision of vaccine clinical trials;
- Expertise in vaccine clinical trial design;
- With basic understanding of epidemiology and statistics.

5.ResearchandDevelopment

Number of recruits:2

Responsibilities

- Able to independently carry out solution preparation, cell culture, virus culture, downstream purification and other operations according to the corresponding operating procedures, which shall meet the research and development requirements of the pipeline projects;
- Based on the requirements of the supervisor, be responsible for the literature research, protocol design, implementation and promotion;
- With the skills for aseptic operation, be able to complete the drafting and implementation of protocolsand take records on time;
- Assist in quality control of project raw data;
- Assist supervisor to do the related lab operation management;

Qualifications

- Major in pharmacy, biology, etc., master degree or above;
- Familiar with relevant regulations of Chinese Pharmacopoeia;
- Strong sense of responsibility, work carefully, preciselyand logically, strong motivationand practical ability;
- Strong ability of project management, able to effectively carry forward the project according to the set goal;
- With a good team spirit and communication skills, and basic statistical analysis ability.

6. Quality Control

Number of recruits:1

Responsibilities

- Based on quality control, improve the technical skills for test and inspection of relevant personnel, sort out methods and key operational points, and improve the ability of relevant personnel to analyze and solve problems;
- Assist related personnel to optimize and develop the test and inspection methods, and complete the validation and implementation of methods according to domestic and foreign laws and regulations in order to achieve the expansion of inspection capabilities;

- Systematically standardize and sort out the daily working process of the laboratory and improve the work efficiency, with reference to international regulations;
- Assist to improve the concepts of quality management for quality control personnel, improve the understanding of domestic and foreign laws and regulations for the team.

Qualifications

- Master degree or above;
- Familiar with GMP system and WHO regulatory requirements, candidate with experience in production quality management or WHO-PQ projectis preferred;
- Good English listening, speaking, reading and writing skills;
- Good written and verbal expression ability;
- Strong organization and coordination ability, able to carry out work according to the actual situation of the company.

7. Quality Assurance

Number of recruits:2

Work Scope:

- Responsible for the management of document system of the company to ensure that the document system from each department complies with related SOP requirements. Collect the domestic and foreign laws and regulations and formulate into the internal documents. Advise on the interpretation of regulations and confirm the interpreting direction together with QA department, provide internal trainings to the company. Promote other operational modules to complete gaps analysis and promote rectifications, etc.

Responsibilities 1:

- Be responsible for complying with company rules and regulations, and actively cooperate with all departments.
- Responsible for the training of statistical courses and knowledge for quality analysis personnel of the company.
- Responsible for quality analysis of company’s products as required.
- Responsible for establishing and improving the documents related to quality analysis.

- Responsible for reviewing all protocols and reports related to quality. analysis, and providingguidance and advice on the application of quality analysis tools and methods.
- Responsible for the completion of ad hoc tasks assigned by leaders.
- Keep technical and trade secrets for the company.

Responsibilities 2:

- Follow the company's rules and regulations, actively cooperate with all departments.
- Responsible for collecting and interpreting domestic and foreign laws and regulations.
- Organize the responsible personnel of other operational modules to complete the gap analysis of the practical application of laws and regulations after interpretation, form the correction plan, and transfer the plan for follow-up implementation.
- Responsible for the overall follow-up and supervision of the gap correction.
- Responsible for ensuring compliance within the company with existing regulatory requirements.
- Responsible for the completion of ad hoc tasks assigned by leaders.

Qualifications

- Education background: Master degree or above;
- Major: Related major in food, chemistry, biology or medicine;
- Experience: experience in quality analysis or statistics is preferred;
- Language skills: English and Chinese shall be used as working languages.