Position: Executive Director of CMO  
Reports to: VP of Pharmaceutical Business  
Available positions: 1  
Job location: Nanjing, China

Job description:

1. Initiate and develop cooperation relationships with national and international resources.  
2. Evaluate the dominant resources such like equipment, capacity, and technicality, identify and track the CMO cooperation opportunities and models.  
3. Draft and track the CMO development schedule, evaluate the CMO result and solve the problems in the project process.  
4. Effectively negotiate the project agreement, and carry out the production plan. Maintain the orderly operation of CMO order process.  
5. Directly manage the CMO project, including the technology transfer, production management evaluation, cost and benefit management and etc..  
6. Directly manage the team, coordinate effective proposal management with the inner groups, maintain the cooperation relationship with the customers and the CMO project proceed smoothly.

Requirements:

1. MS degree in pharmaceutical engineering, pharmacy, biology, chemistry or a related field, oversea working experience is a plus.  
2. 8+ years of drug manufacture industry working experience, at least 3+ years of CMO working experience, possess knowledge of CMO, business development, and drug manufactory.  
3. Have extensive international pharmaceutical industry resources and pharmaceutical business development experience, familiarity with the national and international pharmaceutical industry and the requirement of GMP/CGMP. Possess strong negotiation skills and rich experience in the contract negotiation.  
4. Excellent oral, written and presentation skills in both English and Chinese.
**Position:** FDA On-site Director  
**Reports to:** Vice General Manager of Pharmaceutical Factory  
**Available positions:** 2  
**Job location:** Hainan, China/Nanjing, China

**Job description:**

1. Familiar with laws and regulations such as FDA, and EUGMP, and proficient in related guidelines of international certification.
2. Establishing quality management system accord with US FDA and EUGMP, and auditing quality management documents about FDA.
3. Responsible for FDA certification and test work, and drawing up plans and reports for self-inspection, and following up implementation of rectification of inappropriateness.
4. Responsible for instructions for production, verification and change control of export drugs, giving suggestions in time as well.
5. Carrying out training on FDA or EU regulations for instructions for production, verification, and auditing schemes and reports.
6. Timely organizations for training staff with FDA and EU regulations.
7. Responsible for programs of US FDA certification for application materials, and reply for on-site inspection.

**Requirements:**

1. MS degree or above, majored in medicine, pharmaceutical analysis or related, and with senior professional titles or above.
2. Engaged in pharmaceutical production / technology / quality work, or other work experience in chemistry laboratory analysis, and proficient in GMP. FDA application experience is preferred.
Position: General Manager of Pharmaceutical Factory
Reports to: VP of Pharmaceutical Business
Available positions: 1
Job location: Hainan, China

Job description:

1. Manage the routine work of the factory, responsible for all of the manufacturing management and the production quality. Adopt the board resolution and implement the company's strategy, development plan and operating target, according to the strategic target and operating decision suggested by the board or group.
2. Organize the basic team building, standardize internal management, establish the internal organization structure, and management system, make the operation strategy.
3. To take charge of the review and approval of rewards and punishment rules, payment, performance management system and bonus project.
4. Improve construction of corporation culture, deal with the emergencies of the company.
5. Supervise the implementation of the EHS management.

Requirements:

1. MS degree in pharmacy or a related field, work experience with oversea companies a plus.
2. 10+ years of business management experience, understand the core of advanced business management.
3. Have strategic vision and sharp sense, familiar with the development tend of pharmaceutical industry, manufacturing management and quality management. Familiar with GMP and CGMP.
4. Excellent oral, written and presentation skills in both English and Chinese.
Position: Manager of Quality Assurance  
Reports to: VP of Pharmaceutical Business  
Available positions: 1  
Job location: Nanjing, China

Job description:

1. Design and implement the quality assurance strategy, plan, system, and related institution.  
2. Directly manage the quality assurance work, responsible for the quality assurance management and guidance of subordinate companies and domestic and foreign companies.  
3. According to the annual manufacturing target, make the quality assurance management strategy of Simcere; audit the quality control policy, procedure, institution and operation standards, route and track the implement of quality assurance policy.  
4. Establish the preparations and APIs quality assurance system, ensure the quality assurance system in Simcere satisfying the requirements of domestic and foreign GMP certification.  
5. Authorize final inspection, organize the important special project conference, coordinate the work of every department.  
6. Supervise the quality assurance system and ensure it works efficiently.  
7. Supervise and control the domestic and foreign examination of preparation and APIs in Simcere.

Requirements:

1. BS degree in pharmacy or a related field, work experience with oversea companies a plus. 10+ years quality assurance management working experience (APIs, solid preparations and freeze-dried powder injection).  
2. Familiar with the current situation and prospect of pharmaceutical industry, have interpersonal connections in the industry.  
3. Must have rich experience in foreign preparations, APIs registrations and GMP certifications.  
4. Excellence in cooperation and communication.  
5. Have the ability to deal with the emergency situation.  
6. Must have high level of professional morality level, detail-oriented, high sense of responsibility and efficiency.  
7. Excellent oral, written and presentation skills in both English and Chinese.
Position: QA Director
Reports to: Vice General Manager of Pharmaceutical Factory
Available positions: 2
Job location: Hainan, China/Nanjing, China

Job description:

1. Responsible for establishment, operation, maintenance and improvement of GMP quality management system, and timely supervision, inspection, guidance for GMP implementation.
2. Responsible for the release of materials and products, and QA supervision and inspection of links in a chain of production.
3. Responsible for management of GMP file system.
4. Responsible for regular reviews of quality of products.
5. Responsible for dealing with internal-external audits and certifications, as well as tracking inspection of rectification work, to ensure audits smoothly.
6. Working for organizations for verification and validation, change management, deviation handling, risk assessment, CAPA and other works.
7. Responsible for audits and file maintenance of suppliers.
8. Responsible for department team building and trainings.
9. Responsible for maintenance of department regulations related to environment, occupational health and safety.
10. Other tasks assigned by superiors.

Requirements:

1. MS degree or above, majoring in pharmacy or related.
2. More than 10 years of experience in QA management.
3. Excellent in English listening and speaking.
4. Familiar with GMP specifications and regulations and laws of various countries.
5. Responsibilities, good communication and coordination, and skilled in analysis and problem-solving, and with teamwork spirit.
Position: Chief Process Engineer of Pharmaceutical Factory
Reports to: General Manager of Pharmaceutical Factory
Available positions: 2
Job location: Hainan, China/Nanjing, China

Job description:

1. According to the GMP requirements, responsible for the technical study and improvement. Audit and guide the production technical process and technical standards files.
2. Responsible for the R&D of new production and the improvement of the old production. In charge of the implementation of the R&D technology, organize and implement the new drug R&D project establishment, plan, experiment, submission.
3. Write and review the new drug application document. Develop the new drug which meets the market demands.

Requirements:

1. BS degree in pharmacy or related field; pharmaceutical preparation is a plus.
2. 15+ years drug production working experience in preparation company, familiar with the technologies of all kinds of preparation, and the realistic use of new preparation technologies. Have rich experience in preparation technology transformation and pilot-plant-scale.
3. Familiar with the theory and performance of the preparation production equipment, have successful experience of preparation production problem-solving, especially in preparation technology transformation and pilot-plant-scale.
4. Familiar with GMP requirements of drug register, and the principle of ICH production research, quality evaluation in Europe and America.
5. Be good at organization, cooperation, communication, problem-solving and team-leading.
6. Excellent oral, written and presentation skills in both English and Chinese.
Position: Vice General Manager of Pharmaceutical Factory  
Reports to: General Manager of Pharmaceutical Factory  
Available positions: 2  
Job location: Hainan, China/Nanjing, China

Job description:

1. According to the GMP requirements, help the general manager manage the routine work of the factory, reach the management and development targets.
2. Establish the system of directing manufacture, make and track the manufacture plan, ensure the completion of production task.
3. According to the manufacture plan, track the production progress and coordinate with the workshops to balance the labor, equipment and materials.
4. Organize the production analysis conference, analyze the production situation and suggest the problem-solving method.
5. According to the production demands, make and implement the material purchasing plan, solve the material shortage in time.
6. Ensure that drug production meets the requirement of GMP.
7. Responsible for the technology and quality assurance management during manufacture. Find and solve the problem, report to the general manager if there is something emergency.
8. Improve EHS, organize the safety and environment inspection regularly, implement the EHS management policy and supervise the problem-solving procedure.

Requirements:

1. BS degree in pharmacy or a related field, OR intermediate professional certification or above, work experience with oversea companies a plus.
2. More than 10 years of drug manufacture and quality management experience, at least 3 years management experience. Have professional production related training experience.
3. Familiar with GMP and CGMP.
4. Have strong sense of responsibility and adaption, be good at organization, cooperation, communication and leadership. Strong logical thinking ability, good execution, judgment. Be able to work under pressure.
5. Honest and reliable.
Position: Validation Director  
Reports to: Vice General Manager of Pharmaceutical Factory  
Available positions: 2  
Job location: Hainan, China/Nanjing, China

Job description:

1. Responsible for development of master plan and annual validation plan, and implementation of verification work.
2. Responsible for management processes of validation, and SOP related.
3. Responsible for audits of URS, validation program and report.
4. Lead implementation of validation activities for a state of verification of plant facilities, utilities and equipment; responsible for implementation of validation of analysis method, transportation, cleaning and process.
5. Responsible for deviation and change, and allows for verify internal deviation from the perspective of validation.
6. Responsible for formation, maintenance and management of validation team, following up implementation of program within group.
7. Checking daily operation of tracking inspection for project implementation in accordance with the plan, and deviation investigation with rectification report.
8. Responsible for department team building and trainings.
9. Responsible for maintenance of department regulations related to environment, occupational health and safety.
10. Other tasks assigned by superiors.

Requirements:

1. MS degree or above, majored in pharmacy or related.
2. More than 10 years of experience in QA management.
3. Excellent in English (understanding and spoken).
4. Familiar with GMP specifications and regulations; knowledge of laws of various countries.
5. Responsible, good communication and coordination, and skilled in analysis and problem-solving, and with teamwork spirit.
Position: Vice-President of Pharmaceutical Business
Reports to: President
Available positions: 1
Job location: Nanjing, China

Job description:

1. Manage the entire pharmaceutical business of Simcere, include manufacturing technology, engineering facilities, EHS, lean manufacturing, GMP certification implementation, pharmaceutical internationalization management.
2. According to the annual strategic target and manufacturing target, organize and carry out the annual manufacturing plan.
3. Participate in the management of all manufactures, manage the human resource, materials, and energy which are demanded by production, technology, and engineering facilities of Simcere.
4. Responsible for the audit and guidance of manufactures' equipment procurement and workshop rebuilding.
5. Control and reduce the manufacturing cost, ensure the quality and safety, reach the manufacturing output target.
6. Attract commissioned processing business.

Requirements:

1. MS degree in pharmacy, chemistry or a related field, work experience with oversea companies a plus.
2. 15+ years pharmaceutical industry working experience in famous local company or oversea company and company with foreign capital. 10+ years management experience in manufacturing, familiar with manufacturing management, engineering design, cost control, quality management, warehouse and logistics management.
3. Familiar with the entire operational and technological process of manufacture, especially in manufacturing control and field management.
4. Familiar with certification of quality system and the lean production (LP) mode, expert in every step of manufacturing;
5. Must have high level of professional morality level, detail-oriented, highly the sense of responsibility and efficiency, teamwork and cooperation.
6. Excellent oral, written and presentation skills in both English and Chinese.