【製薬×統括】品質・規制・営業を担うGMポジション｜Confidential企業｜年収1,500万円

Exclusive job

年収1500万円以上！

Job Information

Recruiter
en world Japan K.K

Job ID
1556188

Industry
Medical Device

Non-Japanese Ratio
About half Japanese

Job Type
Contract

Location
Tokyo - 23 Wards

Salary
10 million yen ~ 15 million yen

Work Hours
9:00-18:00

Holidays
完全週休二日制（土曜、日曜、祝日）、年末年始休暇、年次有給休暇

Refreshed
December 1st, 2025 01:00

General Requirements

Minimum Experience Level
Over 6 years

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native

Minimum Education Level
High-School

Visa Status
Permission to work in Japan required

Job Description

【Position】 GENERAL MANAGER OF MARKETING AND SALES (SOKATSU)

【雇用形態】契約社員（正社員切り替え可能性あり）

【就業開始】応相談

【想定年収】15M(ご経験による）

【主な業務内容】
- The Head of Compliance (Sokatsu) in pharmaceuticals has quality, regulation and management skills. The individual coordinates with clients and Contract Manufacturing Organizations (CMOs) involved in the production of medicines on behalf of GRP for future commercial products to all markets.
- Reporting to Japan Country Lead as well as COO, the primary purpose of this position is to lead and manage the Japan Regulatory Affairs strategic and operational activities and oversee and maintain regulatory compliance of GRP products throughout the region. In addition, to facilitate business growth and the delivery of GRP commercial objectives by developing and optimizing regulatory strategies for existing and new business opportunities.
- He/she is responsible for ensuring GRP's product quality in contract manufacturing operations while developing and maintaining relationships. The individual is well organized and has excellent oral and written communication skills to interact effectively with third-party manufacturers to ensure that GRP quality compliance needs are met in a timely manner.
- The individual works closely with CMOs, manufacturing suppliers, Storage Suppliers quality control, regulation, quality systems, product quality owners, and clinical and commercial supply chain operations teams to maintain the supply of pharmaceuticals.
1. A person who is familiar with laws, regulations, and practices related to quality control and safety control, and who can carry out the relevant duties fairly and appropriately.
2. It must meet one of the following requirements:
1） Those who have completed a specialized course in medicine, dentistry, pharmacy, veterinary medicine, or biology at a university or technical college.
2） A person who has completed a specialized course in medicine, dentistry, pharmacy, veterinary medicine, or biology at a high school and has been engaged in quality control or safety control of pharmaceuticals, medical devices, etc. for at least three years.
3） Persons approved by the Minister of Health, Labour and Welfare

2. RESPONSIBILITIES
2.1 RESPONSIBILITIES as per MHLW MO 136

- Assuring that GRP GK MAH Licenses are up to date.
The responsibilities of the General Manufacturing and Sales Manager (Management Supervisor) are as follows.
1. Supervise the Quality Assurance Officer and the Safety Management Officer.
2. Ensure close coordination with the Quality Assurance Department, the Quality Assurance Officer, the Safety Management Department, the Safety Management Officer, and other departments related to their respective operations and their managers.
3. Hold a "Three-Role Mutual Cooperation Meeting" with the Quality Assurance Officer and the Safety Management Officer. Meeting records shall be prepared by the General Manufacturing and Sales Officer and shall be kept after confirmation by the Quality Assurance Officer and the Safety Management Officer.
4. Respect the opinions of the Quality Assurance Officer and the Safety Management Officer.
5. When deemed necessary for quality control and safety management operations, express an opinion in writing to the representative director and keep a copy of it.
6. The Quality and Safety Committee shall be held as necessary.
1） The Quality and Safety Measures Committee shall meet when it is necessary for the General Manufacturing and Sales Manager (Management Supervisor) to evaluate, consider, and make decisions on serious matters related to quality, effectiveness, and safety.
2） The head of the committee shall be the General Manufacturing and Sales Manager (Management Supervisor), and shall consist of the chief safety manager, the quality assurance manager, and the head of the regulatory affairs department, and may be attended by persons other than the members depending on the content of the deliberations. It shall be established with the attendance of more than half of the constituent members.
3） The record of the consultation of the results of the examination shall be prepared by the General Manufacturing and Sales Manager (Management Supervisor), and the relevant departments, the safety management manager, the quality assurance manager, the head of the regulatory affairs department, etc., shall check the consultation record and keep the document.
7. Other necessary matters shall be stipulated in the Quality Control Procedures and Safety Management Procedures.

2.2 Additional Responsibilities based on internal company procedures
1. QA Department Supervision and Support:
- Supervise the QA Manager/ Henseki.
- Respect the opinions of the Henseki.
- Decide on the necessary measures based on reports from the quality assurance manager and instruct the quality assurance department and other departments or persons in charge related to quality control operations to implement them.
- Reviewing Deviation investigations and Change Controls.
- Coordinating audit partners and perform their qualification.
- Developing and Maintaining Quality Technical agreements.
- Reviewing Writing and updating QA procedures in QMS QT9.
- Supporting external audits and inspections from customers or Health Authority.

2. PV Department Supervision and Support:
- Supervise the PV Manager/ Anseki.
- Respect the opinion of the Anseki.
- Supporting Anseki with any request issues as required.
- Supporting external audits and inspections from customers or Health Authority.
- Developing and Maintaining PV Technical agreements.
- Reviewing, Writing, updating PV procedures in QMS QT9.
3. Business Organization Improvement
– Attend management meetings, etc. (a pre-designated person may attend in place of the Sokatsu)
– Assuring that GRP GK MAH Licenses are up to date.
– Communication with Managerial Leaders such as CEO and General Manager to make more efficient and safe business environment.
– Contributing to the continuous improvement of existing department processes and strategies

– Reporting to GRP Headquarters any changes in the Japan regulations that can affect GRP business or its clients' business or products in Japan.
– Taking accountability for the achievement of business goals and objectives.
– Support Client and Customer Communication.
– Support CMO and Supplier QA Qualification.

3 . REPORTING AND INTERACTION
• Reporting to the CEO (MAH)
• Interactions with QA Manager (Hensiki) and Safety Manager (Anseki)
• Interactions with Health authorities (PMDA, Tokyo Metropolitan, MHWL)
• Interactions with Suppliers and Customers

Required Skills

4 . REQUIRED QUALIFICATIONS
The Manager must have the following qualifications:
- Pharmacist with excellent written and verbal communication skills.
- Good leadership and management skills.
- Ability to work with limited supervision and respecting project timelines.
- At least 6 to 7 years-experience in preparing regulatory submissions for PMDA for pharmaceuticals and or biologics.
- At least 4 years managing other team members and acting as GMCO.
- Good understanding of the drug registration and development process.
- Strong knowledge of Japan regulations/guidelines governing regulatory submissions
- Document management, or equivalent technical experience.
- Ability to work in a fast-paced environment that is primarily timeline-driven.
- Ability to manipulate large and complex documents required for submissions.
- Attention to detail with the ability to multi-task.
- Proficiency in MS Word, MS Excel, and Adobe Acrobat is essential.
- Good English speaking and writing abilities.

Company Description