CareerCross by JAC Recruitment

MINARIS REGENERATIVE MEDICINE

Director, Quality Assurance

Job Information

Hiring Company
Minaris Regenerative Medicine Co., Ltd.

Job ID
1521191

Division
Quality Assurance

Industry
Pharmaceutical

Job Type
Permanent Full-time

Location
Kanagawa Prefecture, Yokohama-shi Kanagawa-ku

Train Description
Keihin Tohoku Line (Tokyo-Yokohama), Shin Koyasu Station

Salary
Negotiable, based on experience

Work Hours
09:00 ~ 17:45 休憩時間 60分

Holidays
完全週休二日制 土 日 祝日

Refreshed
March 31st, 2025 10:00

General Requirements

Minimum Experience Level
Over 6 years

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

■Position Summary■
This position will report into COO and will be responsible for the oversight and management of Quality at the Commercial site in Yokohama, Japan. This position is responsible for controlling quality to ensure that product quality manufactured at the site complies with Japanese, US, and EU regulations. Core responsibilities include, but are not limited to, management of resources (human resources and financial resources), development of organization to support commercial manufacturing, hosting client and regulatory inspections, driving inspection readiness and establishing a quality risk management system.

Collaborates with other departments to support organizational and functional strategy. This is a key role

■Essential Functions and Responsibilities■
Below is the summary of the role responsibilities.

- Develop and maintain the quality system in accordance with GCTP
- Reduction of deviations and defective products: Improve customer satisfaction through stable manufacturing and cost reduction through deviation management
- Host self-assessment and external audit (regulatory and client)
- Develop and implement training programs on quality assurance to enhance employee awareness and skills
- Promote quality improvement projects
- APQR preparation and reporting
- Manage cross-functional teams - work with multiple departments to drive quality improvement projects and enhance team collaboration
- Quality risk management
- Improve and enhance quality as Head of Site Quality, align to global QA policy
- Lead and manage quality assurance team
- Set Quality team goals align to global and Japan direction
- Lead team and manage team member's performance to achieve set goals
- Manage human and financial resources for maximum team performance
- Drive quality improve activities and regulatory compliance
- Monitor production process and ensure that all operations comply with GCTP, applicable regulations and SOPs.
- Manage and maintain change management systems
- Assess impact on product quality by deviations, report to stakeholders according to risk and manage necessary remedial actions
- Maintain a high level of quality culture and lead continuous improvement
- Manage site quality risks
- make a batch release decision by the status of manufacturing control and quality control, etc.
- suppliers and contractor’s management

雇用形態
正社員・無期雇用（試用期間 3か月)

年収
想定年収　1,000 万円 ~ 1,500 万円
月給制
月収: 70 万円 ~ / 月額基本給: 70 万円 ~
賞与：年 1 回 (昨年実績: 6月)
昇給：年1回 4月
※表記年収はモデルであり、スキル・経験を考慮の上決定いたします。

勤務地
神奈川県横浜市神奈川区恵比須町1 澁澤ABCビルディング1号館4階
最寄駅　JR 京浜東北線 新子安 駅から徒歩13分
京急本線 京急新子安 駅から徒歩13分
転勤：無し　会社の定める事業所
出向：無し
受動喫煙対策：就業場所　全面禁煙

勤務時間
本ポジションは管理監督職
就業時間 09:00 ~ 17:45（休憩時間 60分）
残業 月 10 時間 ~ 20 時間程度
※スーパーフレックスタイム制(コアタイムなし)

休日休暇
年間休日 123 日
完全週休二日制 土 日 祝日 年末年始

- その他一斉年休行使日5日有
- サポート休暇、特別休暇
- その他休暇:産前産後休業、配偶者出産休暇、結婚休暇、忌慰休暇、公用休暇、罹災休暇、転勤休暇、リフレッシュ休暇、介護休暇、子の看護休暇、不妊治療休暇、母性健康管理休暇、アディショナル休暇、公傷休業等
- 年間有給休暇：有給休暇は入社時から付与されます(入社7ヶ月目には最低10日以上)

手当・福利厚生

- 交通費：全額支給
- 社会保険：健康保険 厚生年金 雇用保険 労災保険
- 残業手当：管理監督職のため、労働基準法41条により、労働時間、休憩、休日の割増賃金の規定は適用されません。
- 福利厚生：退職金有:確定給付企業年金制度(DB)、確定拠出型年金制度(DC)

Required Skills

■Competencies■

- Ability to think strategically and tactically (detail-oriented)

- Strong collaborative and influencing skills and ability to work well in a cross-functional, matrixed environment
- Analytical and problem-solving skills
- Strong written and oral communication skills
- Meeting management/facilitation skills/teamwork
- Ability to multi-task team is essential
- Flexible and able to adapt to company growth and evolving responsibilities.
- Ability to work autonomously in an entrepreneurial, fast paced environment.
- Strong business acumen

■Qualifications■

- Minimum 5 years' experiences in the manufacturing of pharmaceuticals, quasi-drugs, regenerative medicine, etc., and minimum 3 years' experiences in quality assurance and in a management role
- Experience in a responsible person in a GCTP or GMP organization (preferable Quality Assurance Manager, Batch Release Judgement)
- Knowledge to perform quality assurance duties in the manufacturing industry for pharmaceuticals, quasi-drugs, regenerative medicine, etc.
- Knowledge and experiences to fully understand manufacturing regulations and GCTP requirements and to train and lead employees in quality team
- Knowledge of ICH, PIC/S, GCTP, and GMP necessary to perform quality assurance and the ability to apply them to the job.
- Experience with global regulations (US, EU)
- Native level of Japanese and strong English capability
- Bachelor Diploma from a university or higher in a science-related

Company Description