【800～1500万円】Device Quality Assurance Manager/Sr. Manager

医療機器×医薬品　バイオベンチャーでの募集です。 メディカルGQP・GMP・品...

募集職種

人材紹介会社
株式会社ジェイ エイ シー リクルートメント

採用企業名
医療機器×医薬品　バイオベンチャー

求人ID
1563536

業種
医薬品

会社の種類
外資系企業

雇用形態
正社員

勤務地
東京都 23区

給与
800万円 ~ 1500万円

休日・休暇
【有給休暇】初年度 10日 入社1か月目から付与 【休日】完全週休二日制 土 日 祝日 夏季休暇 年末年始 ※詳細はオファー時...

更新日
2025年11月27日 16:00

応募必要条件

キャリアレベル
中途経験者レベル

英語レベル
流暢

日本語レベル
ネイティブ

最終学歴
高等学校卒

現在のビザ
日本での就労許可が必要です

募集要項

【求人No NJB2337444】
Position Summary
This position will directly report to Head of Device Quality Assurance （QA） department and have a responsibility for handling and leading operation for quality management processes for the medical devices. It will provide opportunities to work closely with a multidisciplinary team in the group while mainly focusing on post market quality assurance matters management of licensees and product release for clinical trials.

Key Roles and Responsibilities
・Lead post market activities including monitoring complaint trends maintaining risk management file performing products

and parts inspection among others.
・Analyse and interpret data applying statistical methods to identify trends anomalies and opportunities for improvement.
・Write review and maintain documentation of processes required for device quality management system.
・Evaluate and manage suppliers both in Japan and overseas including collaborating with them to address quality challenges.
・Work closely with a global multidisciplinary team to oversee feedback and complaint handling nonconformance control corrective and preventive actions change control supplier assessment among others.
・Maintain working knowledge of current regulations standards and guidance related to quality management systems and medical devices.

スキル・資格

Desired Education Skills and Experience
・A minimum of a bachelor’s degree in science engineering or a related field.
・At least 3+ years of experience and knowledge of relevant medical device industry. Candidates with more experience will be considered for a senior position.
・Understanding of PMD Act relevant regulations and guidelines in Japan.
・Thorough knowledge is expected of ISO 13485.
・Knowledge of FDA 21 CFR Part 820 is a plus.
・Experience in quality assurance operations listed below:
  └Quality management system
  └CAPA nonconformance feedback and complaint handling
  └Product release and recall
  └External and internal audits and
  └Inspection by regulatory authorities notified bodies and/or customers.
・Comprehensive knowledge and practical experience in medical device risk management （e.g. ISO 14971）.
・Hands on experience applying statistical tools and techniques to calculate sample sizes analyse data identify trends and support process improvements.
・Excellent verbal and written communication skills and ability to read write and speak Japanese.
・Experience in communicating in English with business partners and ability to read write and speak in English is strongly preferred.

会社説明

ご紹介時にご案内いたします