CareerCross by JAC Recruitment

【900～1100万円】【Kidney technology transformed】安全管理責任者（Anseki）

安全性情報（臨床開発・製販後GVP）のご経験のある方は歓迎です。

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
非公開

求人ID
1550188

業種
医療機器

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
900万円 ~ 1100万円

勤務時間
09:00 ～ 17:30

休日・休暇
【有給休暇】初年度 10日 1か月目から 【休日】完全週休二日制 土 日 年末年始 年間休日 124日 完全週休二日制 （土、…

更新日
2025年07月10日 15:56

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
大学卒： 学士号

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 NJB2293723】
■Role of the Anseki:
・ Plan direct and implement all quality activities for Our products and services within the Japan Region acting as the Anseki or Safety Controller of Medical Devices ensuring consistent timely and effective post market controls. Representing the organization as the Anseki within Japan for all in country quality matters.
・ Assuring appropriate product quality monitoring and reporting by executing in country quality activities such complaint management reportability decisions and regulatory reporting field corrective action planning and execution risk assessment

interfacing with customers and liaising with PMDA and responding directly to queries.
・ Partnering closely with the global Our Quality organization to establish and meet enterprise Key Process Indicators （KPI）; plan deploy and execute global processes.
・ Acting as the Japan Quality Subject Matter Expert source of coaching and guidance for leaders peers and subordinates. Partnering closely with the Sokatsu or General Marketing Supervisor Medical Devices and the Hinseki or Domestic Quality Assurance Manager.

■Key Accountabilities:
・ Provide leadership within the Japan Quality function; support and execute the Japan Quality strategy act as Subject Matter Expert for Quality in region and coach train and mentor peers and team member.
・ Responsible for safety team and safety controlling activities
・ Monitor safety controlling activities and generate necessary records
・ Report and escalate issues related to safety controls
・ Collaborate with global post market surveillance team
・ Establish effective communication with the Japanese health authorities （e.g. PMDA）.
・ Ensure compliance to policies and procedures. State the opinion in writing to top management and responsible officers when deemed necessary to perform the activities appropriately and while being compliant with regulations.
・ Facilitate the collaborations between the department of quality or anufacturing controls and the department of safety controls. Provide information or give instruction to manufacturers foreign registered manufacturers distributors and medical institutions as necessary for the purposes of domestic safety Controlling activities.
・ Partner to ensure the appropriate safety controls monitoring the performance and quality of products in the field to conform to established company standards necessary to maintain lasting consumer satisfaction.
・ Responsible for the activities for safety controls. Ensure that domestic operations for safety controls are executed appropriately and smoothly. Ensure product quality within the Japan region by assuring the necessary safety and post market controls.
・ Collect the information on the product quality （including defective and potentially defective products） in the country and from overseas. Report them to leadership so that necessary and appropriate actions shall be taken and relevant records shall be created.
・ Interface with internal partners customers and regulatory bodies regarding product complaints vigilance reporting and product recalls.
・ Ensure that regulatory activities are consistent with local regulatory authority requirements.
・ Facilitate regulatory inspections by authorized Body auditors or local regulatory authorities.
・ Review government policy changes with regards the regulatory function and develops policy position papers and advocacy to support the interests of the organization with regards policy development.
・ Ensure that the Company’s agreed quality standards （including ISO13485） are maintained with regard to its products procedures policies operations and customer contact.

スキル・資格

■Requirements
・ Minimum undergraduate degree （e.g. Bachelor of Science Bachelor of Arts） preferably in in engineering or sciences.
・ 3 years of relevant experience with 1 year of leadership experience or advanced degree （e.g. Masters PhD） with a minimum of 1 years of relevant experience with 1 year of leadership experience.

■Relevant Experience and Knowledge
・ Experience and in depth knowledge of the Japan Region and international Medical Devices regulations including ISO13485 and MDSAP. Experience communicating and partnering with PMDA regarding product safety.
・ Preferred qualified or registered as Anseki
・ Required 2+ years in a role working in Japan region preferably with experience in multiple countries languages and cultures.
・ Good communication channel with regulatory body and industry working groups.
・ Demonstrated strong people leadership skills and experience.
・ Strong project management skills and ability to deliver under tight deadlines and pressure.
・ Experience across multiple products and/or geographies
・ Sound understanding of and experience with the management of Quality systems ISO13485.
・ Excellent verbal and written English communication and interpersonal skills.

会社説明

ご紹介時にご案内いたします