Quality System Manager
质量体系经理

Location: **Beijing**
Starting date: **ASAP**

ABOUT THE COMPANY
关于企业

Our client, founded in 1977 with the headquarter in France, is a medical device company specialized in the field of interventional neuroradiology.
我们的客户，成立于1977年，总部位于法国，是一家专门从事介入神经放射学领域的医疗器械公司。

MISSIONS
工作介绍

The quality manager is responsible for establishing and maintaining QMS procedures and QMS compliance to local standards and regulations, also be responsible for PMS activities and reporting.
质量经理负责建立和维护质量管理体系（QMS）程序，并确保 QMS 符合当地的标准和法规。此外，质量经理还负责产品管理（PMS）活动和报告。

Cooperate with regulatory, operation, marketing, sales, supply chain departments, responsible for the establishment and implementation of various procedures to ensure pre-market and post-market activities compliance with global local regulations and standards.
与法规、运营、市场、销售、供应链部门合作，负责建立和实施各种程序，以确保市场前和市场后的活动符合全球和当地的法规和标准。

Act as liaison between Company and NMPA in terms of quality system and PMS related topics, including but not limited to any form of audit, events/incidents reporting, submit many kinds of reports etc.
作为企业与国家药品监督管理局（NMPA）之间的联络人，质量经理负责在质量体系和产品管理系统（PMS）相关议题上进行沟通协调，包括但不限于各种形式的审计、事件/事故报告、提交各类报告等。

Set up regular meetings with global to update China quality department progress, issues, risks, solutions.
定期与全球团队会面，更新中国质量部门的进展、问题、风险和解决方案。

Collect and analyze quality regulations from NMPA, QMS and other quality requirements related to the products.
收集并分析 NMPA 的质量法规、QMS 以及其他与产品相关的质量要求。

Responsible for establishing quality management system and products' quality control; ensure QMS effective operation for the Company.
负责建立质量管理系统和产品质量控制；确保公司的质量管理体系有效运作。

External Audit: Support China local team in audits for any kind of internal and external audits (including but not limited to NMPA national/provincial level inspection in China, NMPA overseas on-site audit, etc.) Work with external auditors, ensure QMS compliance to NMPA and ISO13485 requirements.
外部审计：支持中国本地团队进行各类内外部审计（包括但不限于国家药品监督管理局国家/省级检查、国家药品监督管理局海外现场审计等）。与外部审计师合作，确保质量管理体系符合国家药品监督管理局和 ISO13485的要求。

Internal Audit: Prepare internal audit plan, act as internal audit team leader, coordinate and solve major problems or findings.
内部审计：准备内部审计计划，担任内部审计团队领导，协调并解决主要问题或发现。

Prepare quality training plan and coordinate the execution. Keep trainings records for internal and external audits.
准备质量培训计划并协调执行。保持内部和外部审计的培训记录。

Collaborate with relevant stakeholders to review reportable events, assess regulatory requirements, and ensure timely and accurate reporting to NMPA in compliance with local regulations.
与相关利益相关者合作，审查可报告事件，评估法规要求，并确保按照当地法规及时准确地向国家药品监督管理局报告。

Prepare and submit to NMPA the Annual Self-Inspection Reports on time per year.
按时准备并提交国家药品监督管理局的年度自检报告。

Prepare for Periodic Risk Evaluation Report per product on time per year.
按时准备每个产品的周期性风险评估报告。

In charge of Chinese language labeling and IFU and work with branch to facilitate the process and operation.
负责中文标签和使用说明书，并与其他分支机构合作以简便流程和操作过程。

Support Chinese IFU review for registration submission.
支持中国使用说明书审核以用于注册提交。

Support product registration submissions from the QA side, coordinating with global QA the collection and generation of any document requested for the NMPA submission.
从 QA 方面支持产品注册提交，与全球 QA 协调，收集和生成国家药品监督管理局提交所需的任何文件。

Key Relationship / Customer Expectations:
关键关系/客户期望：
Interact with all levels of management from local country manager, sales, marketing, regulatory affairs.

与本地国家经理、销售、市场、法规事务等各级管理层进行互动。

Work closely with China local health authority (NMPA) as required.
按要求与中国当地卫生部门（国家药品监督管理局）密切合作。

Work in close cooperation with company's global quality team and ensure China quality comply with company global quality
与公司全球质量团队紧密合作，确保中国质量符合公司全球质量标准。

REQUIREMENT
要求

Bachelor degree or above, biomedical engineering, electronics or other related majors preferred.
本科及以上学历，生物医学工程、电子或其他相关专业优先。

More than 7 years' experience in medical device quality management.
7年以上医疗器械质量管理经验。

Master of English in oral and writing.
精通英语口语和写作。

ISO13485 well established knowledge.
ISO13485知识。

Familiar with various quality analysis tools.
熟悉各种质量分析工具。

Experience with NMPA inspection and audit.
有国家药品监督管理局检查和审计经验。

Familiar with NMPA GMP for local manufacturing site class III devices.
熟悉国家药品监督管理局针对本地生产场所三类器械的药品生产质量管理规范。

APPLICATION
申请方式

Please send your English and Chinese CV to
请发送中英文简历至

Bj-HR@ccifc.org