CareerCross by JAC Recruitment

【810～万円】＜研究開発・メディカルアフェアーズ統括本部＞Principal Scientist Quality Audit…

日本イーライリリー株式会社での募集です。 臨床開発QC・GCP監査のご経験のあ…

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
日本イーライリリー株式会社

Job ID
1502200

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
8 million yen ~ Negotiable, based on experience

Work Hours
08:45 ～ 17:30

Holidays
【有給休暇】有給休暇は入社後2ヶ月目から付与されます 初年度 10日 2か月目から 【休日】完全週休二日制 年末年始 完全週休…

Refreshed
March 27th, 2025 12:00

General Requirements

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

【求人No NJB2250916】
This job position is for a GCP medical auditor. The position is office based located at the Lilly Kobe affiliate office.

Position Brand Description:

The Quality Auditor is part of the Global Quality Auditing and Compliance （GQAAC） division and provides quality assurance through the execution of internal and external audits in support of pharmaceutical development non clinical and clinical research product commercialization pharmacovigilance and consumer information quality （CIQ） for Lilly. Through auditing the Global Quality Auditor assures that GXP operations conducted or sponsored by Lilly are performed in accordance with company standards policies procedures and practices and are compliant with current regulatory requirements and expectations applicable guidelines and industry standards.

GQAAC is operating as a valued business partner and taking a proactive approach to further enhancing the quality status of business operations and regulatory compliance. The Quality Auditor plays a key part in contributing to the implementation of this strategic approach to quality auditing oversight.

Key Objectives/Deliverables:

The following activities will be performed according to current GQAAC procedures guidelines and tools. These responsibilities are not intended to be all inclusive:

Auditing:

Scheduling preparing conducting and reporting GQAAC audits and assessments of GXP operations both internally and externally （contracted） to assess the level of compliance with company standards policies practices and procedures and current regulations and guidelines.
Participate in or lead the risk assessment of GXP operations in support of generating the GQAAC risk based annual audit plan.
Appropriately escalate any compliance issues.
Meet the requirements outlined in quality standards quality manuals policies procedures and tools.
This implies establishment and maintenance of a comprehensive knowledge of all applicable regulations technical knowledge and training to meet these responsibilities.

Global Quality · Business Related Responsibilities:

Participate in or lead the preparation and/or review of standards policies procedures and guidelines that are used to establish quality requirements when needed.
Participate in or lead the preparation of organizational metrics and trending of audit findings when required.
Provide audit related advice to GXP operations on the interpretation of corporate and regulatory GxP requirements （standards/policies/procedures） related to quality management when required.
Establish and maintain relationships with relevant business areas and regulatory authorities including support for regulatory inspections when required.
Provide technical expertise in identifying formulating assembling and delivering quality and compliance education to customers as required.
Personnel Development:

Maintain good interpersonal and communication skills with auditees and business areas with particular emphasis on verbal and technical writing skills.
Complete required training for the roles identified in the Individual Training Plan （ITP）
Be continually aware of current industry trends and regulatory agency interpretation of GxP requirements.
Seek self development in GxP areas （e.g. attend training courses conferences or association meetings） and share such information and knowledge with other members of the group or company to increase internal intelligence.
Participate or lead divisional improvement efforts including Six Sigma projects and departmental teams.
Support training and qualification of other auditors.
Business title: Principal Scientist Quality Auditor GQAAC

Required Skills

Minimum Requirements:
・Relevant experience（s） （minimum of 5 years） within the GCP medical area at Lilly or within the pharmaceutical environment.
・Good oral and written communication skills in English.
・Ability to communicate effectively in Japanese language” in the requirement.
・Experience working with Third Party Organizations.
・The ability to understand detailed scientific information while remaining anchored in the “Big Picture”.
・Ability to interpret and apply regulations regulatory guidance codes and public expectations and identify and recommend compliance changes as appropriate.
・Excellent interpersonal skills ability to remain constructive and civil in difficult situations.
・Ability to deliver timely and professional communications （oral and written） with precision and clarity to all levels of the organization.
・Experience working on a global team and sharing knowledge.
・Experience with computers and entering data into databases.
・Good analytical/problem solving skills.

Education Requirements:
Bachelors Degree （or equivalent work experience） in physical or biological sciences engineering or other technical area.

Travel Requirements:
Domestic and international travel is required to fulfill these job responsibilities. Must be able to travel up to 40% （duration 1 2 weeks） sometimes on short notice.

Additional Preferences:
・Experience in technical report writing.
・Work under pressure on multiple tasks concurrently and meet deadlines in a fast paced work environment with frequent interruptions and changing priorities.

・Proven ability to think and analyze from a process perspective. Project management skills.
・Process information to identify linkages and trends and apply findings to compliance strategies as well as to individual assignments.
・Work independently as well as collaboratively within a global team environment.
・Deliver constructive feedback to customers while providing a high level of customer service.
・Ability to influence and manage change/conflict.
・Establish and maintain effective working relationships at all levels internal and external to Lilly.
・Ability to think on your feet and be pragmatic in decision making.

Company Description

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